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# TRANSMITTAL FORM

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| | |
|---|---|
| Application Number | 10/662,697 |
| Filing Date | September 15, 2003 |
| First Named Inventor | William J. Boyle et al. |
| Art Unit | 3731 |
| Examiner Name | Sarah K. Webb |
| Total Number of Pages in This Submission | |
| Attorney Docket Number | ACSES 65470 (2309D) |

**ENCLOSURES** *(Check all that apply)*

- [X] Fee Transmittal Form
- [X] Fee Attached
- [ ] Amendment / Reply
- [ ] After Final
- [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
- [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [X] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
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- [ ] Status Letter
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|---|---|---|---|
| Firm Name | FULWIDER PATTON LLP | | |
| Signature | | | |
| Printed name | THOMAS H. MAJCHER | | |
| Date | JULY 14, 2006 | Reg. No. | 31,119 |

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| Signature | | | |
| Typed or printed name | THOMAS H. MAJCHER | Date | JULY 14, 2006 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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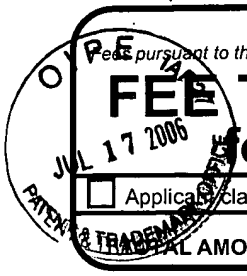


Fees pursuant to the Consolidated Appropriatons Act, 2005 (H.R. 4818).

# FEE TRANSMITTAL for FY 2006

☐ Applicant claims small entity status. See 37 CFR 1.27

| TOTAL AMOUNT OF PAYMENT | ($) | $500.00 |
|---|---|---|

| Complete if Known | |
|---|---|
| Application Number | 10/662,697 |
| Filing Date | September 15, 2003 |
| First Named Inventor | William J. Boyle et al. |
| Examiner Name | Sarah K. Webb |
| Art Unit | 3731 |
| Attorney Docket No. | ACSES-65470 (239D) |

## METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Deposit Account Number: 06-2425 Deposit Account Name: FULWIDER PATTON LLP

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## FEE CALCULATION (All the fees below are due upon filing or may be subject to a surcharge.)

### 1. BASIC FILING, SEARCH, AND EXAMINATION FEES

| | FILING FEES | | SEARCH FEES | | EXAMINATION FEES | | |
|---|---|---|---|---|---|---|---|
| | | Small Entity | | Small Entity | | Small Entity | |
| Application Type | Fee ($) | Fee ($) | Fee ($) | Fee ($) | Fee ($) | Fee ($) | Fees Paid($) |
| Utility | 300 | 150 | 500 | 250 | 200 | 100 | |
| Design | 200 | 100 | 100 | 50 | 130 | 65 | |
| Plant | 200 | 100 | 300 | 150 | 160 | 80 | |
| Reissue | 300 | 150 | 500 | 250 | 600 | 300 | |
| Provisional | 200 | 100 | 0 | 0 | 0 | 0 | |

### 2. EXCESS CLAIM FEES

| Fee Description | Fee ($) | Small Entity Fee ($) |
|---|---|---|
| Each claim over 20 (including Reissues) | 50 | 25 |
| Each independent claim over 3 (including Reissues) | 200 | 100 |
| Multiple dependent claims | 360 | 180 |

| Total Claims | | Extra Claims | Fee ($) | | Fee Paid ($) |
|---|---|---|---|---|---|
| _____ | - 20 or HP = | _____ | x $50.00 | = | $0.00 |

HP = highest number of total claims paid for, if greater than 20.

| Indep. Claims | | Extra Claims | Fee ($) | | Fee Paid ($) |
|---|---|---|---|---|---|
| _____ | - 3 or HP = | _____ | x $200.00 | = | $0.00 |

HP = highest number of independent claims paid for, if greater than 3.

| Multiple Dependent Claims | |
|---|---|
| Fee ($) | Fee Paid ($) |
| _____ | _____ |

### 3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listing under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

| Total Sheets | | Extra Sheets | | Number of each additional 50 or fraction thereof | | Fee ($) | | Fee Paid ($) |
|---|---|---|---|---|---|---|---|---|
| _____ | - 100 = | 0 | / 50 | 0 | (round up to a whole | x $250.00 | = | $0.00 |

### 4. OTHER FEE(S)

| | Fee Paid ($) |
|---|---|
| Non-English specification, $130 fee (no small entity discount) | |
| Other (e.g., late filing surcharge): Appeal Brief | $500.00 |

## SUBMITTED BY

| | | | | | |
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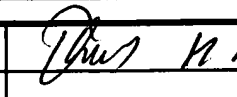
| Signature |  | Registration No. (Attorney/Agent) | 31,119 | Telephone | 310 824 5555 |
| Name (Print/Type) | THOMAS H. MAJCHER | | | Date | JULY 14, 2006 |

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Thomas H. Majcher, Reg. No. 31,119



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | |
|---|---|
| In re application of: | Examiner: Sarah K. Webb |
| William J. Boyle et al. | Group Art Unit 3731 |
| Serial No. 10/662,697 | Docket No. ACSES-65470 (2309D) |
| Filed: September 15, 2003 | |
| For: DEPLOYMENT AND RECOVERY CONTROL SYSTEMS FOR EMBOLIC PROTECTION DEVICES | July 14, 2006<br>Los Angeles, California 90045 |

APPEAL BRIEF

Mail Stop Appeal Brief - PATENTS
Commissioner for Patents
P.O. Box 1450
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This Appeal Brief is responsive to the Notice of Panel Decision from Pre-Appeal Brief Review, dated June 15, 2006. This Appeal Brief is being filed within the term provided under 37 C.F.R. § 41.36.

## INTRODUCTION

The present invention relates generally to filtering devices used to capture embolic material that may be created and released into a body vessel when an interventional procedure is being performed in a stenosed or occluded region of the body vessel. The present invention is more particularly directed to recovery systems for recovering and removing these filtering

devices from the body vessel after the procedure has been performed. The invention provides a recovery system which is less likely to cause the body vessel to straighten as it is advanced over a guide wire to retrieve the filtering device. This feature is particularly useful when the recovery system is being deployed on a curved portion of the body vessel. Additionally, the recovery system of the present invention has increased flexibility at its distal portion to better enable the system to more easily negotiate the often tortuous anatomy of the vasculature and improve tracking over the guide wire. The present application, U.S. Serial No. 10/662,697 was filed on September 15, 2003. This application is a divisional application of Serial No. 09/845,758, filed April 30, 2001, which issued as U.S. Patent No. 6,645,223.

A Notice of Appeal from the final Office Action of December 22, 2005 was filed on May 1, 2006. The one month deadline from the receipt of the Notice of Panel Decision from Pre-Appeal Brief Review, dated June 15, 2006, is July 15, 2006 and this Appeal Brief is being filed within the term permitted under 37 C.F.R. § 41.36.

## REQUEST FOR ORAL ARGUMENT

An oral argument is requested.

## I. REAL PARTY IN INTEREST

The real party in interest is ADVANCED CARDIOVASCULAR SYSTEMS, INC. This application was originally assigned by the inventors, WILLIAM J. BOYLE, BENJAMIN C. HUTER, CHARLES R. PETERSON, DONALD E. SCHWARTEN, and RICHARD S. STACK to ADVANCED CARDIOVASCULAR SYSTEMS, INC., by Assignment respectively executed on April 9, 2001, April 11, 2001, April 12, 2001 and April 21, 2001 which was recorded by the Patent Office on July 16, 2001 beginning at Reel 011983, Frame 0290.

## II. RELATED APPEALS AND INTERFERENCES

None.

## III. STATUS OF CLAIMS

This patent application has pending claims under consideration. Of the originally-filed 62 claims, claims 1-34 were canceled in a preliminary amendment. Claims 63-74 were subsequently added during prosecution. Pending claims 35-74 were finally rejected in a final Office Action dated December 22, 2005.

Claims 35-74 are pending in the application and the rejections of claims 35-74 are being appealed. A copy of the claims appealed is attached hereto as Exhibit 1.

Claims 35-40, 42-50, 52-74 were rejected under 35 U.S.C. § 102(e) as being anticipated by Daniel et al. (U.S. Patent No. 6,171,327).

Claims 41 and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Daniel et al. (U.S. Patent No. 6,171,327) in view of Heyn et al. (U.S. Patent No. 5,201,757).

Claim 38 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Daniel et al. (U.S. Patent No. 6,171,327).

(Copies of U.S. Patent Nos. 6,171,327 and 5,201,757 are attached hereto as Exhibit 2)

## IV. STATUS OF AMENDMENTS

**Preliminary Amendment Dated September 15, 2003** (a copy of which is attached as Exhibit 3)

In a Preliminary Amendment dated September 15, 2003, the Applicants:

- canceled original claims 1-34 without prejudice.

**First Office Action Dated September 24, 2004** (a copy of which is attached as Exhibit 4)

In a first Office Action dated September 24, 2004, the Examiner:

- rejected claims 35-40, 42-50, 52-54 and 58-62 under 35 U.S.C. § 102(e) as being anticipated by Daniel et al. (U.S. Patent No. 6,171,327); and

- rejected claims 41 and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Daniel et al. in view of Heyn et al. (U.S. Patent No. 5,201,757).

**Amendment Dated December 20, 2004** (a copy of which is attached as Exhibit 5)

In an Amendment Dated December 20, 2004, the Applicants:

- amended independent claims 1, 45 and 54;
- presented new claims 63-67; and
- presented argument to overcome the rejections under 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a)

**Final Office Action Dated March 14, 2005** (a copy of which is attached as Exhibit 6)

In a final Office Action dated March 14, 2005, the Examiner:

- rejected claims 35-40, 42-50, 52-67 under 35 U.S.C. § 102(e) as being anticipated by Daniel et al. (U.S. Patent No. 6,171,327); and
- rejected claims 41 and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Daniel et al. in view of Heyn et al. (U.S. Patent No. 5,201,757).

**Amendment Dated May 12, 2005** (a copy of which is attached as Exhibit 7)

In an Amendment dated May 12, 2005, the Applicants:

- amended independent claims 35, 45 and 51; and
- presented argument to overcome the rejections under 35 U.S.C. § 102(e) and 35 U.S.C. § 102(e)

**Advisory Action Dated June 10, 2005** (a copy of which is attached as Exhibit 8)

In an Advisory Action dated June 10, 2005, the Examiner refused entry of the Amendment dated May 12, 2005.

**RCE Dated June 14, 2005** (a copy of which is attached as Exhibit 9)

In an RCE dated June 14, 2005, Applicants resubmitted the previously presented Amendment.

**Third Office Action Dated July 7, 2005** (a copy of which is attached as Exhibit 10)

In a third Office Action dated October 7, 2005, the Examiner:

- rejected claims 35-40, 42-50, 52-67 under 35 U.S.C. § 102(e) as being anticipated by Daniel et al. (U.S. Patent No. 6,171,327);

- rejected claims 41 and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Daniel et al. in view of Heyn et al. (U.S. Patent No. 5,201,757);

- rejected claims 38 and 48 under 35 U. S. C. 112, first paragraph, on the grounds that the specification does not reasonably provide enablement for the inner catheter having a greater column strength than the recovery sheath; and

- rejected claims 35-38, 45-48 and 54-57 under the judicially-created doctrine of obviousness-type double patenting over claims 1-17 of U. S. Patent No. 6,569,184.

**Amendment Dated October 7, 2005** (a copy of which is attached as Exhibit 11)

In an Amendment dated October 7, 2005, the Applicants:

- amended independent claims 35, 45 and 54;

- added new claims 68-74;

- filed a terminal disclaimer to overcome the double-patenting rejection;

- presented argument why the specification enabled the structure of claims 38 and 48; and

- presented argument to overcome the rejections under 35 U.S.C. § 102(e) and 35 U.S.C. § 102(e).

**Final Office Action Dated December 22, 2005** (a copy of which is attached as Exhibit 12)

In a final Office Action dated December 22, 2005, the Examiner:

- rejected claims 35-40, 42-50, 52-74 under 35 U.S.C. § 102(e) as being anticipated by Daniel et al. (U.S. Patent No. 6,171,327);

- rejected claims 41 and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Daniel et al. in view of Heyn et al. (U.S. Patent No. 5,201,757); and

- rejected claim 38 under 35 U.S.C. § 103(a) as being unpatentable over Daniel et al. (U.S. Patent No. 6,171,327).

**Response Dated February 21, 2006** (a copy of which is attached as Exhibit 13)

In a Response dated October 7, 2005, the Applicants:

- presented argument to overcome the rejections under 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a)

**Advisory Action Dated March 29, 2006** (a copy of which is attached as Exhibit 14)

In an Advisory Action dated June 10, 2005, the Examiner refused entry of the Amendment dated May 12, 2005.

**Pre-Appeal Brief Request for Review Dated May 1, 2006** (a copy of which is attached as Exhibit 15)

In a Pre-Appeal Brief Request for Review Dated May 1, 2006, the Applicants:

- presented argument to overcome the rejections under 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a)

**Notice of Appeal Dated May 1, 2006** (a copy of which is attached as Exhibit 16)

A Notice of Appeal dated May 1, 2006 was filed by the Applicants.

## V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The present invention is directed to a recovery system (page 16, ¶ 026, FIGS. 3-5, # 70) which utilizes an inner catheter (page 16, ¶ 026, FIGS. 3-5, # 72) capable of being introduced over a guide wire (FIGS. 3-5, # 18), along with a recovery sheath (page 16, ¶ 026, FIGS. 3-5, # 76) which extends co-axially over the inner catheter. Control handles (page 16, ¶ 026, FIGS. 3-5, #s 82 & 86) are attached to the proximal ends of both the inner catheter and recovery sheath. The inner catheter and recovery sheath are simultaneously advanced over the guide wire (page 16, ¶ 026, FIGS. 3-5) to collapse and recover the deployed filtering device (page 16, ¶ 027, FIGS. 3-5, # 14) located at the distal end of the guide wire.

The inner catheter includes a distal portion (page 16, ¶ 026, FIGS. 3-5, # 78) made from a length of flexible tubing (FIGS. 3-5, # 78). This distal portion remains uncovered by the recovery sheath and extends away from the distal end of the recovery sheath when the inner catheter and recovery sheath are advanced along the guide wire (page 16, ¶ 026, FIGS. 3-5). After the inner catheter reaches the filtering device in the body vessel, the recovery sheath can be advanced distally to "track" over the distal portion of the inner catheter to collapse and draw the filtering device into the recovery sheath (page 16, ¶ 026, FIGS. 3-5).

This distal portion of the inner catheter provides several advantageous features to the recovery system. The distal portion can be made from a highly flexile material (page 17, ¶ 028 and page 19, ¶ 033) which is less likely to cause the body vessel to straighten as it is advanced over the guide wire to retrieve the filtering device (page 17, ¶ 028). The length of tubing forming the distal portion provides a "track" over which the recovery sheath moves once the inner catheter reaches the filtering device (pages 17 & 18, ¶ 029-030, FIGS. 3-5). This smaller diameter distal portion actually helps to maintain the curvature of the body vessel by minimizing the possibility that body vessel will "straighten" as the larger diameter recovery sheath is advanced over the length of tubing and the deployed filtering device (page 17, ¶ 028). This feature is particularly useful when the recovery system is being deployed on a curved portion of the body vessel (page 17, ¶ 028). Additionally, the increased flexibility of the distal portion better enables the catheters to more easily negotiate the often tortuous anatomy of the vasculature and improves tracking over the guide wire (page 17, ¶ 028).

**Independent claim 35 is supported by at least the following references to the specification, reference characters, and figures**:

35. A system for recovering an embolic protection device which includes a guide wire (FIGS. 3-5, # 18) and expandable filter (FIGS. 3-5, # 14) disposed thereon from a body vessel (FIGS. 3-5, # 24), comprising:

an inner catheter (FIGS. 3-5, # 72) having a distal portion (FIGS. 3-5, # 78) and a proximal end and being moveable along the guide wire, the distal portion including a length of flexible tubing (FIGS. 3-5, # 78);

a control handle (FIGS. 3-5, # 82) attached to the proximal end of the inner catheter;

a recovery sheath (FIGS. 3-5, # 76) having a distal end (FIG. 3-5, # 80) and a proximal end; and

a control handle (FIGS. 3-5, # 86) attached to the proximal end of the recovery sheath, wherein the inner catheter is capable of being loaded inside the recovery sheath (FIGS. 3-5, # 74) with the distal portion of the inner catheter extending distally beyond the distal end of the recovery sheath (FIG 3) when the inner catheter and recovery sheath are being advanced along the guide wire for placement in proximity to the expandable filter of the embolic protection device, the recovery sheath having sufficient column strength (FIGS. 4-5) to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover (page 17-18, ¶¶ 029-030) to reduce the possibility that the recovery sheath will straighten the body vessel (page 17, ¶ 028) when deployed in a curved portion of the body vessel.

**Independent claim 45 is supported by at least the following references to the specification, reference characters, and figures**:

45. An embolic protection system for deployment in a body vessel, comprising:

a guide wire (FIGS. 3-5, # 18) having a distal end;

an expandable filter (FIGS. 3-5, # 14) located near the distal end of the guide wire;

an inner catheter (FIGS. 3-5, # 72) having a distal portion (FIGS. 3-5, # 78) and a control handle (FIGS. 3-5, # 82) located at a proximal end , wherein the inner catheter is capable of being introduced over the guide wire and the distal portion includes length of flexible tubing (page 16, ¶ 026, FIGS. 3-5); and

a recovery sheath (FIGS. 3-5, # 76) having a distal end (FIGS. 3-5, # 80) and a control handle (FIGS. 3-5, # 86) located at a proximal end, wherein the inner catheter is capable of being loaded inside of a lumen (FIGS. 3-5, # 74) of the recovery sheath, wherein the distal portion of the inner catheter extends distally beyond the distal end of recovery sheath when being advanced along the guide wire to retrieve the expandable filter (FIG. 3), the recovery sheath having sufficient column strength (FIGS. 4-5) to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover (page 17-18, ¶¶ 026, FIGS. 3-5, # 70) to reduce the possibility that the recovery sheath will straighten the body vessel (page 16, ¶ 026, FIGS. 3-5, # 70) when deployed in a curved portion of the body vessel.

**Independent claim 54 is supported by at least the following references to the specification, reference characters, and figures**:

54. A method of recovering an embolic protection device (FIGS. 1-2, # 12) which includes a guide wire (FIGS. 3-5, # 18) and an expandable filter (FIGS. 3-5, # 14) from a body vessel (FIGS. 3-5, # 24), comprising:

loading an inner catheter (FIGS. 3-5, # 72) inside a recovery sheath (FIGS. 3-5, # 76), wherein the inner catheter has a distal portion (FIGS. 3-5, # 78) which extends beyond the distal end (FIGS. 3-5, # 80) of the recovery sheath, the distal portion including a length of flexible tubing having sufficient length to allow the distal end of a recovery sheath to pass thereover (page 16, ¶ 026, FIGS. 3-5) to reduce the possibility that the recovery sheath will straighten the body vessel (page 17, ¶ 028) when deployed in a curved portion of the body vessel;

introducing the inner catheter and recovery sheath over the guide wire;

advancing the distal end of the inner catheter to a position adjacent to the expanded filter (FIG. 3);

locking the inner catheter onto the guide wire (page 17, ¶ 029);

tracking the recovery sheath over the distal portion of the inner catheter and the expanded filter to collapse the expanded filter (page 11-18, ¶ ¶ 029-030, FIGS. 4-5).

**Independent claim 68 is supported by at least the following references to the specification, reference characters, and figures:**

68. An embolic protection system for deployment in a body vessel, comprising:

a guide wire (FIGS. 3-5, # 18) having a distal end;

an expandable filter (FIGS. 3-5, # 14) having a particular longitudinal length (FIGS. 3-5) located near the distal end of the guide wire;

an inner catheter (FIGS. 3-5, # 72) having a distal portion (FIGS. 3-5, # 78) and a control handle (FIGS. 3-5, # 82) located at a proximal end, wherein the inner catheter is capable of being introduced over the guide wire and the distal portion includes a length of flexible tubing (FIG. 3-5, # 78) at least as long as the longitudinal length of the expandable filter (FIG. 3); and

a recovery sheath (FIGS. 3-5, # 76) having a distal end (FIGS. 3-5, # 80) and a control handle (FIGS. 3-5, # 86) located at a proximal end, wherein the inner catheter is capable of being loaded inside of a lumen (FIGS. 3-5, # 74) of the recovery sheath, wherein the distal portion of the inner catheter extends distally beyond the distal end of recovery sheath (FIG. 3) when being advanced along the guide wire to retrieve the expandable filter, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover (page 17, ¶ 028) to reduce the possibility that the recovery sheath will straighten the body vessel (page 17, ¶ 028) when deployed in a curved portion of the body vessel.

## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

In the Final Office action dated December 22, 2005, the Examiner rejected claims 35-40, 42-50 and 52-74 under 35 U.S.C. § 102(e) as being anticipated by Daniel et al. (U.S. Patent No. 6,171,327). Dependent claims 41 and 51 were rejected under 35 U.S.C. § 103(a) over Daniel et al. (U.S. Patent No. 6,171,327) in view of Heyn et al. (U.S. Patent No. 5,201,757). Claim 38 was rejected under 35 U.S.C. § 103(a) over Daniel et al.(U.S. Patent No. 6,171,327).

In view of the Examiner's rejections, Appellants respectfully submit that the issues are as follows:

Issue 1. Are claims 35-40, 42-50, 52-67 and 70-74 unpatentable under 35 U.S.C. § 102(e) as anticipated by Daniel et al. (U.S. Patent No. 6,171,327)?

Issue 2. Are claims 68 and 69 unpatentable under 35 U.S.C. § 102(e) as anticipated by Daniel et al. (U.S. Patent No. 6,171,327)?

Issue 3. Are claims 41 and 51 unpatentable under 35 U.S.C. § 103(a) as obvious over Daniel et al. (U.S. Patent No. 6,171,327) in view of Heyn et al. (U.S. Patent No. 5,201,757).

Issue 4. Is claim 38 unpatentable under 35 U.S.C. § 103(a) as obvious over Daniel et al. (U.S. Patent No. 6,171,327).

## VII. ARGUMENT

### ISSUE 1

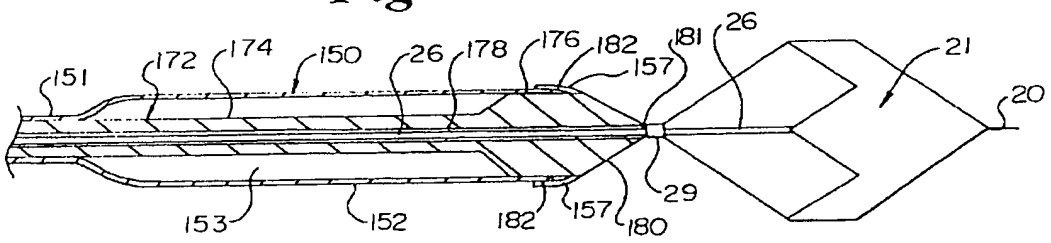
In the final Office action dated December 22, 2005, the Examiner rejected claims 35-40, 42-50 and 52-67 and 70-74 under 35 U.S.C. § 102(e) as being anticipated by Daniel et al. (U.S. Patent No. 6,171,327). Claims 35-53, 63-66 and 70-74 are apparatus claims directed to a system for recovering an embolic protection device. Claims 54-62 and 67 are method claims directed to a method for recovering an embolic protection device. Each claim includes the recitation of an inner catheter capable of being loaded within a recovery sheath. Additionally, each claim recites that the inner catheter has a distal portion including a length of flexible tubing which extends distally beyond the distal end of the recovery sheath when the inner catheter and recovery sheath are advanced over a guide wire. Each claim also requires the distal portion of the inner catheter to have sufficient length to allow the distal end of the recovery catheter to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed.

Appellants submit that the Examiner has misinterpreted the Daniel et al. patent and has misconstrued the pending claims by disregarding specific structural recitations appearing in the

claims. The Examiner has relied solely on the embodiments appearing in figures 20-26 of Daniel et al. in rejecting the claims at issue. The embodiments shown in figures 20-23 of Daniel et al. are directed to the catheter portion of the device and figures 24-26 show the control handles associated with the catheters.

Figure 20 from Daniel et al is reproduced below for ease of reference.

*Fig. 20*




Daniel et al. is directed to a system for recovering a filter device disposed at the end of a guide wire. The Daniel et al. recovery system includes an inner catheter 172 and a retrieval catheter 150 having an enlarged housing 152 for storing the collapsed filter. The inner catheter 172 includes a transversely enlarged insert 176 which fills the inside diameter of the housing 152 in order to create an atraumatic tip. This insert 176 has a short tapered tip portion 180 which barely extends out of the housing 152. This short tapered portion 180 creates a smooth tapered tip profile and helps to prevent the distal end 157 of the housing 152 from "snowplowing" into the wall of the body vessel as the catheter is advanced over the guide wire 26.

One main issue in dispute is whether the small tapered tip 180 located at the distal end of the inner member 172 of Daniel et al. constitutes a "length of flexible tubing" having "sufficient length" to reduce the possibility that the recovery sheath will straighten the body vessel once advanced over the length of tubing. Again, as previously mentioned above, in Appellants' invention, the distal portion (the length of flexible tubing) is made from a highly flexile material which is less likely to cause the body vessel to straighten as it is initially advanced over the guide wire to retrieve the filtering device. Moreover, once the length of tubing reaches the filtering device, it provides a "track" over which the recovery sheath moves to help maintain the curvature of the body vessel by minimizing the possibility of the artery will "straighten" as the

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Thomas H. Majcher, Reg. No. 31,119



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|---|---|---|
| Appl. No. | : | 10/662,697 |
| Applicants | : | William J. Boyle et al. |
| Filed | : | September 15, 2003 |
| Title | : | DEPLOYMENT AND RECOVERY CONTROL SYSTEMS FOR EMBOLIC PROTECTION DEVICES |
| Art Unit | : | 3731 |
| Examiner | : | Sarah K. Webb |
| Docket No.: | : | ACSES-65470 (2309D) |
| Customer No. | : | 24201 |

Los Angeles, California
May 1, 2006

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents
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Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

INTRODUCTION

The present invention relates generally to filtering devices used to capture embolic material that may be created and released into a body vessel when an interventional procedure is being performed in a stenosed or occluded region of the body vessel. The present invention is more particularly directed to recovery systems for recovering and removing these filtering devices from the body vessel after the procedure has been performed.

The recovery system of the present invention utilizes an inner catheter capable of being introduced over a guide wire, along with a recovery sheath which extends co-axially over the inner catheter. Control handles are attached to the proximal ends of both the inner catheter and recovery sheath. The inner catheter and recovery sheath are simultaneously advanced over the guide wire to collapse and recover the deployed filtering device located at the distal end of the guide wire.

The inner catheter includes a distal portion made from a length of flexible tubing. This distal portion remains uncovered by the recovery sheath and extends away from the distal end of the recovery sheath when the inner catheter and recovery sheath are advanced along the guide wire. After the inner catheter reaches the filtering device in the body vessel, the recovery sheath can be advanced

distally to "track" over the distal portion of the inner catheter to collapse and draw the filtering device into the recovery sheath.

This distal portion of the inner catheter provides several advantageous features to the recovery system. The distal portion can be made from a highly flexile material which is less likely to cause the body vessel to straighten as it is advanced over the guide wire to retrieve the filtering device. The length of tubing forming the distal portion provides a "track" over which the recovery sheath moves once the inner catheter reaches the filtering device. This smaller diameter distal portion actually helps to maintain the curvature of the body vessel by minimizing the possibility of the artery will "straighten" as the larger diameter recovery sheath is advanced over the distal portion and the deployed filtering device. This feature is particularly useful when the recovery system is being deployed on a curved portion of the body vessel. Additionally, the increased flexibility of the distal portion better enables the catheters to more easily negotiate the often tortuous anatomy of the vasculature and improves tracking over the guide wire.

NOTICE OF APPEAL

A Notice of Appeal from the final Office Action of December 22, 2005 is being filed concurrently herewith along with the appropriate fee.

ISSUES ON APPEAL

At issue is whether claims 35-40, 42-50, 52-74 are unpatentable under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,171,327 to Daniel et al. ("the Daniel patent"). A secondary issue is whether dependent claims 41 and 51 are obvious under 35 U.S.C. § 103(a) over the Daniel patent in view of U.S. Patent No. 5,201,757 to Heyn et al. ("the Heyn patent"). The Daniel patent is directed to a system for recovering a filter device disposed at the end of a guide wire. The Daniel recovery system includes an inner catheter 172 and a retrieval catheter 150 having an enlarged housing 152 for storing the collapsed filter. The inner catheter 172 includes a transversely enlarged portion 176 which fills the inside diameter of the housing 152 in order to create an atraumatic tip. This portion 176 has a short tapered portion 180 which barely extends out of the housing 152. This short tapered portion 180 creates a smooth tapered tip profile and helps to prevent the distal end 157 of the housing 152 from "snowplowing" into the wall of the body vessel as the catheter is advanced over the guide wire.

A copy of the pending claims is attached hereto as Exhibit A. A copy of the drawings is attached hereto as Exhibit B. A copy of the final Office Action dated December 22, 2005 is attached hereto as Exhibit C. The Daniel patent is attached as Exhibit D. The Heyn patent is attached as Exhibit E. The Advisory Action dated April 22, 2006 is attached as Exhibit F.

ARGUMENT

Claims 35-53, 63-66 and 68-74 are apparatus claims directed to a system for recovering an embolic protection device. Claims 54-62 and 67 are method claims directed to a method for recovering the embolic protection device. Each claim includes the recitation of an inner catheter having a distal portion including a length of flexible tubing capable of being loaded within a recovery sheath. Each claim also requires the distal portion of the inner catheter to extend distally beyond the distal end of the recovery sheath when the inner catheter and recovery sheath are advanced over a guide wire with the distal portion of the inner catheter having sufficient length to allow the distal end of the recovery catheter to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed.

Claims 35-40, 42-50, 52-74 were rejected under 35 U.S.C. § 102(e) as being anticipated by the Daniel patent. Appellant submits that the Examiner has misinterpreted the Daniel patent, has relied on an embodiment (Fig. 19) in the Daniel patent in rejecting claims which lacks the basic structure recited in the present claims, and has misconstrued the pending claims by disregarding specific structural recitations appearing in the claims.

One main issue in dispute is whether the small tapered tip 180 located at the distal end of the inner member 150 of the Broome patent constitutes a "length of flexible tubing" having sufficient length to allow the distal end of the recovery catheter to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel. Initially, the Examiner had taken the position that this short tapered portion 180 meets the structural requirements of each claim because it is part of the catheter and is a flexible tube. Appellant has consistently argued that the claims require more that just a length of tubing extending out of the recovery sheath since the claims also require the distal portion to have a length of flexible tubing having sufficient length to allow the distal end of the recovery catheter to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel. Apparently, the Examiner has given little or no consideration for this structural limitation recited in each claim. Appellant has argued that the inner catheter 172 in FIG. 20 or component 372

in FIG. 23 of the Daniel patent includes only a small tapered portion 180 which barely extends beyond the recovery sheath 150 and does not constitute a distal portion of the inner catheter as this component is defined in the claims. This distal tapered portion 180 is simply the end of a large insert 176 designed to fill the lumen of the recovery sheath's housing and provide a soft and atraumatic tip. This portion 176 remains within the lumen of the housing during usage with only a small portion of the tapered portion 180 extending beyond the distal end of the recovery sheath.

Appellant submits that if this distal tip portion 180 is construed to be a "length of tubing," as the Examiner contends, then it must be capable of allowing the distal end of the recovery sheath to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel. This structural recitation in the claims cannot be disregarded. Due to its tapered structure, this tapered portion 180 doesn't even make contact with the retrieval catheter 150. Appellant submits that it cannot and does not function as a track over which the recovery sheath moves to reduce the possibility that the retrieval catheter will straighten a curved portion of the body vessel.

In the last Office Action, the Examiner has taken the additional position that the distal portion of the inner catheter is more than just this tapered tip portion 180. The Examiner's new position, found at page 6, lines 1-7 of the final Office Action (Exhibit C), reads as follows:

> Examiner does not consider only the tip of the inner catheter to be the distal portion of the inner catheter. The "distal portion" can be any length of the inner catheter distal to the most proximal point. Therefore, the Daniels device includes a length of the inner catheter that is at least as long as the filter. The "recovery sheath does "move over" the entire inner catheter, so this argument is not found to be persuasive.

However, the only portion of the inner catheter which arguably could be construed as a flexible tube is the portion of the inner catheter which extends proximally, not distally, to the tip portion 176. In use, this portion of the inner catheter in the Daniels device remains completely covered by the recovery sheath. Again, the claims recite that the distal portion of the inner member remains distal of the distal end of the recovery sheath when advanced along the guide wire.

The error in the Examiner's position is further found in statements made in the Advisory Action dated April 22, 2006 (Exhibit F). The Examiner states as follows:

> Clearly a length of this tube (172) extends distally beyond the sheath (150. The figures show only one of the many possible relevant positions between the components, so the inner tube could be moved to extend farther beyond the sheath.

However, the inner tube could not possibly be moved to extend farther beyond the sheath. Control handles attached to the inner catheter and recovery catheter prevent the inner catheter from extending any further than is shown in Figures 20 and 23. (See figures 24-26 and Column 9, line 51-Column 11, line 2 of Daniel patent). Therefore, the Examiner's position is incorrect.

The Examiner also has relied on the embodiment of figure 19 to support the position that the recovery sheath tracks over the inner catheter. However, this embodiment lacks the basic inner catheter recited in the claims. At page 2, lines 16-18 of the final Office Action (Exhibit C), the Examiner states the following:

> The recovery sheath (151) tracks over the distal portion on the inner catheter to retrieve the filter, as shown in Figure 19.

However, this embodiment doesn't have an inner catheter, no less an inner catheter with a distal portion made from a length of flexible tubing. The embodiment of figures 19 simply shows a tapered insert 58 attached to a guide wire which is movable within the housing 52 of the recovery catheter.

Claims 41 and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Daniel patent in view of the Heyn patent. Since the Daniel patent lacks the basic components recited in the claims, its combination with the Heyn patent fails to achieve the structure recited in the claims.

In summation, the Daniel patent simply fails to disclose the presently claimed invention. It is therefore urged that claims 35-74 are allowable over the cited art.

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Appl. No. | : | 10/662,697 |
| Applicants | : | William J. Boyle et al. |
| Filed | : | September 15, 2003 |
| Title | : | DEPLOYMENT AND RECOVERY CONTROL SYSTEMS FOR EMBOLIC PROTECTION DEVICES |
| Art Unit | : | 3731 |
| Examiner | : | Sarah K. Webb |
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| Customer No. | : | 24201 |

Los Angeles, California
May 1, 2006

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NOTICE OF APPEAL FROM THE EXAMINER

TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Dear Sir:

Applicant hereby appeals to the Board of Patent Appeals and Interferences from the decision of the Examiner dated December 22, 2005, rejecting each of pending claims 35-74.

A check in the amount of $500 is enclosed herewith for the fee for this Notice of Appeal. The Commissioner is hereby authorized, however, to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 06-2425. A duplicate copy of this paper has been enclosed.

Respectfully submitted,

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Thomas H. Majcher, Reg. No. 31,119



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| | | |
|---|---|---|
| Appl. No. | : | 10/662,697 |
| Applicants | : | William J. Boyle et al. |
| Filed | : | September 15, 2003 |
| Title | : | DEPLOYMENT AND RECOVERY CONTROL SYSTEMS FOR EMBOLIC PROTECTION DEVICES<br>Divisional of U.S. Patent No. 6,645,223 (09/845,758 filed 4/30/01) |
| Art Unit | : | 3731 |
| Examiner | : | Sarah K. Webb |
| Docket No.: | : | ACSES-65470 (2309D) |
| Customer No. | : | 24201 |

Los Angeles, California
February 21, 2006

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## RESPONSE TO FINAL OFFICE ACTION

This Response is made to the final Office Action of December 22, 2005, a response to which is due March 22, 2006.

Claims start on page 2.

Remarks start on page 10.

AMENDMENTS TO THE CLAIMS:

The below listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1 – 34 (Canceled).

35. (Previously presented) A system for recovering an embolic protection device which includes a guide wire and expandable filter disposed thereon from a body vessel, comprising:

an inner catheter having a distal portion and a proximal end and being moveable along the guide wire, the distal portion including a length of flexible tubing;

a control handle attached to the proximal end of the inner catheter;

a recovery sheath having a distal end and a proximal end; and

a control handle attached to the proximal end of the recovery sheath, wherein the inner catheter is capable of being loaded inside the recovery sheath with the distal portion of the inner catheter extending distally beyond the distal end of the recovery sheath when the inner catheter and recovery sheath are being advanced along the guide wire for placement in proximity to the expandable filter of the embolic protection device, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel.

36. (Original) The system of claim 35, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

37. (Original) The system of claim 35, wherein:

the recovery sheath has greater column strength than the inner catheter.

38. (Original) The system of claim 35, wherein:

the inner catheter has greater column strength than the recovery sheath.

39. (Original) The system of claim 35, further including:

a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

40. (Original) The system of claim 35, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

41. (Original) The system of claim 35, wherein:

the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

42. (Original) The system of claim 41, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

43. (Original) The system of claim 42, wherein:

the control handle of the inner catheter is movable relative to the control handle of the recovery sheath.

44. (Original) The system of claim 35, further including:

means for locking the inner catheter onto the guide wire.

45. (Previously Presented) An embolic protection system for deployment in a body vessel, comprising:

a guide wire having a distal end;

an expandable filter located near the distal end of the guide wire;

an inner catheter having a distal portion and a control handle located at a proximal end, wherein the inner catheter is capable of being introduced over the guide wire and the distal portion includes length of flexible tubing; and

a recovery sheath having a distal end and a control handle located at a proximal end, wherein the inner catheter is capable of being loaded inside of a lumen of the recovery sheath, wherein the distal portion of the inner catheter extends distally beyond the distal end of recovery sheath when being advanced along the guide wire to retrieve the expandable filter, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel.

46. (Original) The system of claim 45, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

47. (Original) The system of claim 45, wherein:

the recovery sheath has greater column strength than the inner catheter.

48. (Original) The system of claim 45, wherein:

the inner catheter has greater column strength than the recovery sheath.

49. (Original) The system of claim 45, further including:

a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

50. (Original) The system of claim 45, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

51. (Original) The system of claim 45, wherein:

the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

52. (Original) The system of claim 51, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

53. (Original) The system of claim 52, wherein:

the control handle of the inner catheter is movable relative to the control handle of the recovery sheath and further including means for locking the control handles together.

54. (Previously Presented) A method of re covering an embolic protection device which includes a guide wire and an expandable filter from a body vessel, comprising:

loading an inner catheter inside a recovery sheath, wherein the inner catheter has a distal portion which extends beyond the distal end of the recovery lumen, the distal portion including a length of flexible tubing having sufficient length to allow the distal end of a recovery sheath to pass thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel;

introducing the inner catheter and recovery sheath over the guide wire;

advancing the distal end of the inner catheter to a position adjacent to the expanded filter;

locking the inner catheter onto the guide wire;

tracking the recovery sheath over the distal portion of the inner catheter and the expanded filter to collapse the expanded filter.

55. (Original) The method of claim 54, further comprising:

removing the recovery sheath, inner catheter, and embolic protection device from the body vessel.

56. (Original) The method of claim 54, wherein:

the recovery sheath may be up to approximately 15 centimeters shorter than the inner catheter.

57. (Original) The method of claim 54, wherein:

the distal portion of the inner catheter may extend up to 10 centimeters beyond the distal end of the recovery sheath when being advanced over the guide wire.

58. (Original) The method of claim 54, wherein:

a control handle is located at the proximal end of the inner catheter and a control handle located at the proximal end of the recovery sheath.

59. (Original) The method of claim 58, wherein:

the control handle of the inner catheter can be locked to the control handle of the recovery sheath.

60. (Original) The method of claim 54, wherein:

after the distal end of the inner catheter is advanced to a position adjacent to the expanded filter, a torque control device is attached to the guide wire and placed in an abutting relationship with the proximal end of the inner catheter to lock the inner catheter onto the guide wire.

61. (Original) The method of claim 58, wherein:

after the distal end of the inner catheter is advanced to a position adjacent to the expanded filter, a torque control device is attached to the guide wire and placed in an abutting relationship with the control handle of the inner catheter to lock the inner catheter onto the guide wire.

62. (Original) The method of claim 58, wherein:

control handle of the recovery sheath is advanced distally to position the recovery sheath over the distal portion of the inner catheter and the expanded filter to collapse the expanded filter.

63. (Previously Presented) The system of claim 35, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

64. (Previously Presented) The system of claim 35, wherein:

the flexible tubing of the distal portion of the inner catheter is more flexible than the recovery sheath.

65. (Previously Presented) The system of claim 45, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

66. (Previously Presented) The system of claim 35, wherein:

the flexible tubing of the distal portion of the inner catheter is more flexible than the recovery sheath.

67. (Previously Presented) The method of claim 54, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

68. (Previously Presented) An embolic protection system for deployment in a body vessel, comprising:

a guide wire having a distal end;

an expandable filter having a particular longitudinal length located near the distal end of the guide wire;

an inner catheter having a distal portion and a control handle located at a proximal end, wherein the inner catheter is capable of being introduced over the guide wire and the distal portion includes a length of flexible tubing at least al long as the longitudinal length of the expandable filter; and

a recovery sheath having a distal end and a control handle located at a proximal end, wherein the inner catheter is capable of being loaded inside of a lumen of the recovery sheath, wherein the distal portion of the inner catheter extends distally beyond the distal end of recovery sheath when being advanced along the guide wire to retrieve the expandable filter, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel.

69. (Previously Presented) The system of claim 68, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

70. (Previously Presented) The system of claim 45, further including:

a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

71. (Previously Presented) The system of claim 45, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

72. (Previously Presented) The system of claim 45, wherein:

the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

73. (Previously Presented) The system of claim 51, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

74. (Previously Presented) The system of claim 52, wherein:

the control handle of the inner catheter is movable relative to the control handle of the recovery sheath and further including means for locking the control handles together.

## REMARKS

This Response is made to the final Office Action of December 22, 2005. Claims 35-74 are pending in this application. Applicants respectfully request reconsideration of all the pending claims in view of the remarks presented below.

Claims 35-40, 42-50, 52-74 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,171,327 to Daniel et al. ("the Daniel patent"). Applicants submit that the Examiner has misinterpreted the Daniel patent, has relied on an embodiment (shown in Fig. 19) in the Daniel patent which lacks even the basic structure recited in the present claims, and may have misconstrued the claims by failing to appreciate the particular function and the interrelationship of elements recited in the present claims. For at least these reasons, addressed in greater detail below, Applicants believe that the Daniel patent should be withdrawn as an anticipatory reference.

Applicants submit that the Daniel patent fails to disclose a number of the elements, along with the structural relationships between these elements, as recited in the pending claims. First, the presently claimed inventions defined by claims 35, 45, 54 and 68 recite a system for recovering an embolic protection device which includes an inner catheter with a distal portion having a length of flexible tubing of sufficient length which allows the distal end of the recovery sheath to track thereover and reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel. This length of tubing of the inner catheter extends distally beyond the distal end of the recovery sheath when being advanced over the guide wire. However, such a structure is simply not shown in the Daniel patent. Applicants note that the inner catheter, which the Examiner has identified as component (172) in FIG. 20 or component (372) in FIG. 23 of the Daniel patent, includes only a small tapered portion (180) which barely extends beyond the recovery sheath (150) during usage. Applicants strongly disagree with the Examiner's position that this distal tapered portion (180) somehow constitutes a "length of tubing" which extends beyond the distal end of the recovery sheath. Moreover, this distal tapered portion (180) is simply the end portion of a large

insert or portion (176) which is housed within the recovery sheath and is designed to provide a relatively soft and atraumatic tip to the composite catheter. This portion (176) remains within the lumen or housing of the recovery sheath during usage with only a small portion of the tapered portion (180) extending beyond the end of the recovery sheath.

The Examiner's position regarding the identity of the location of the distal portion of the inner catheter can be found at page 6, lines 1-7 of the Office Action which reads as follows:

> The distal portion (172, 180) is part of the inner catheter, which is a flexible tube. Examiner does not consider only the tip of the inner catheter to be the distal portion of the inner catheter. The "distal portion" can be any length of the inner catheter distal to the most proximal point. Therefore, the Daniels device includes a length of the inner catheter that is at least as long as the filter. The "recovery sheath does "move over" the entire inner catheter, so this argument is not found to be persuasive.

While the Examiner may be correct in stating that the distal portion (172, 180) is part of the inner catheter, the only portion of the inner catheter which arguably could be construed as a flexible tube is the portion of the inner catheter which extends proximally, not distally, to this portion (176). Again, this portion (176) is designed to fill in the lumen of the housing (152) and remains within the housing during use, with only the small tapered portion (180) extending distally out of the housing. In this manner, a tip is created to prevent the housing from scraping the sides of the body vessel as the retrieval catheter is advanced within the patient. However, this portion (176) and tapered portion (180) do not constitute a length of flexible tubing as recited in the claims.

If this distal tip portion 180 is indeed construed to be a "length of tubing," as the Examiner contends, then it still must be capable of allowing the distal end of the recovery sheath to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel. However, the tapered tip portion 180 doesn't even make contact with the recovery sheath, no less

allowing the recovery sheath to track thereover to reduce the chances of the recovery sheath straightening a curved portion of the body vessel.

The Examiner's above-stated position as to what constitutes the distal portion of the inner member is further incorrect. In the claims, the distal portion cannot be "any length of the inner catheter distal to the most proximal point" as stated by the Examiner. Rather, the present claims recite that the distal portion of the inner catheter extends distally beyond the distal end of the recovery sheath when the inner catheter and recovery sheath are being advanced over the guide wire. The only portion of the inner catheter of the Daniels device which extends beyond the recovery sheath is this small tapered tip 180. Therefore, the Examiner's position that the "distal portion" can be any length of the inner catheter distal to the most proximal point simply misconstrues the particular structure recited in the present claims. For this same reason, the distal portion of the Daniel device cannot be at least as long as the filter, as stated by the Examiner at page 6 of the Office Action, but at best only as long as the length of the tapered portion (180).

Applicants further believe that there are other examples where the Examiner may have misconstrued the present claims which may have lead the Examiner to incorrectly apply the Daniel patent to the claims. For example, at page 5, lines 11-13 of the Office Action, the Examiner states as follows:

> Claims 35 recites "inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility ..."

However, claims 35 states that it is the distal portion (i.e., the length of tubing extending beyond the distal end of the recovery sheath) of the inner catheter which has the sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility. ... Therefore, after reading this statement by the Examiner, Applicants respectfully submit that the Examiner may have misconstrued the claim language and improperly applied the Daniel patent based upon improper claim construction.

The Examiner also has relied upon an embodiment in the Daniel patent to support the position that the recovery sheath tracks over the inner catheter. However, as can be clearly seen in the drawings, this embodiment lacks even the basic inner catheter recited in the claims. At page 2, lines 16-18, the Examiner states as follows:

> The recovery sheath (151) tracks over the distal portion on the inner catheter to retrieve the filter, as shown in Figure 19.

However, this embodiment of the Daniel patent doesn't even have an inner catheter, no less an inner catheter with a distal portion having a length of flexible tubing of sufficient length which allows the distal end of the recovery sheath to track thereover and reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel. The embodiment of Figures 17-19 simply shows a tapered insert 58 attached to a guide wire and movable within the housing 52 of the recovery catheter. There is no inner catheter. For at least this reason, Applicants submit that the Examiner has failed to meet the Examiner's burden of citing a reference which includes a recovery sheath which tracks over the distal portion on the inner catheter as recited in the present claims.

For at least all of the reasons stated above, Applicants believe that the Daniel patent fails to disclose the structure recited in the pending claims. Accordingly, Applicants again respectfully request the Examiner to withdraw the Daniel patent as an anticipatory reference.

Claims 41 and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Daniel patent in view of U.S. Patent No. 5,201,757 to Heyn et al. ("the Heyn patent"). Claim 38 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the Daniel patent itself. In view of the remarks addressed above with respect to the presently claimed invention defined by claims 35 and 45, it is believed that the particular combination of the Daniel patent with the Heyn patent, or the Daniel patent itself, fails to achieve the claimed structure. Applicants respectfully request the Examiner to withdraw the obviousness rejections against claims 38, 41 and 51.

In view of the foregoing, it is respectively urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above remarks, Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/662,697 | 09/15/2003 | William J. Boyle | ACS 65470 (2309D) | 9777 |

24201 7590 03/29/2006

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|---|---|
| WEBB, SARAH K | |
| ART UNIT | PAPER NUMBER |
| 3731 | |

DATE MAILED: 03/29/2006

Advisory Action

Please find below and/or attached an Office communication concerning this application or proceeding.

FINAL REJECTION

2 - MONTH RESPONSE DUE: _____
3 - MONTH RESPONSE DUE: _____
NOTICE OF APPEAL DUE:
(6-MONTH PERIOD ENDS) June 22, 2006

| Advisory Action Before the Filing of an Appeal Brief | Application No. 10/662,697 | Applicant(s) BOYLE ET AL. | |
|---|---|---|---|
| | Examiner Sarah K. Webb | Art Unit 3731 | |

*--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

THE REPLY FILED 27 February 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments were not found to be persuasive. Applicant asserts that the distal end of the inner tubing does not extend distally beyond the recovery sheath in the Daniel's patent. The embodiment in Figure 20 has an inner cahteter. Clearly, a length of this tube (172) extends distally beyond the sheath (150). The figures show only one of many possible relative positions between the components, so the inner tube could be moved to extend farther beyond the sheath. Even though only a short length of the inner tube is illustrated as extending beyond the sheath (150), the short length meets the broad limitation "a length." The disclosed function of the Daniel's inner tube is irrelevant as long as Daniel's meets the structural requirements.

larger diameter recovery sheath is advanced over the length of tubing and the deployed filtering device.

Initially during prosecution, the Examiner took the position that this short tapered tip portion 180 meets the structural requirements of each claim simply because it is part of an inner catheter and constitutes a flexible tube. However, Appellants have consistently argued that this tapered tip is not a length of flexible tubing in accordance with the present invention. Also, even assuming that this tapered tip portion 180 does constitute a length of flexible tubing, Appellants submit that the claims require more that just any length of tubing extending out of the recovery sheath since the claims also require the distal portion to include flexible tubing of a sufficient length to allow the distal end of the recovery catheter to track thereover and to reduce the possibility that the recovery sheath will straighten the body vessel. Apparently, the Examiner has given little or no consideration for this structural limitation recited in each claim.

Appellants submit that if this distal tip portion 180 is construed to be a "length of tubing," as the Examiner contends, then it must be capable of allowing the distal end of the recovery sheath to track thereover and be of such length as to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel. This structural recitation in the claims cannot be disregarded. However, due to its tapered structure, the tapered tip portion 180 of the Daniel device doesn't even make contact with its retrieval catheter 150. Appellant submits that it cannot, and does not, function as a track over which the recovery sheath moves to reduce the possibility that the retrieval catheter will straighten a curved portion of the body vessel. Moreover, the tapered tip portion 180 is so short that it barely extends out of the housing 152 of the retrieval catheter 150. Accordingly, due to its lack of size, this tapered tip portion 180 does nothing to help prevent the body vessel from straightening as catheter system is advanced along the guide wire to collapse the filter and does nothing to prevent the retrieval catheter 150 from straightening the body vessel as it is deployed.

In the final Office Action dated December 22, 2005, the Examiner has taken the additional position that the distal portion of the inner catheter is more than just this tapered tip portion 180. Appellants respectfully point out that the Examiner's position is incorrect. The

Examiner's new position, found at page 6, lines 1-7 of the final Office Action (Exhibit 12), reads as follows:

> Examiner does not consider only the tip of the inner catheter to be the distal portion of the inner catheter. The "distal portion" can be any length of the inner catheter distal to the most proximal point. Therefore, the Daniels device includes a length of the inner catheter that is at least as long as the filter. The "recovery sheath does "move over" the entire inner catheter, so this argument is not found to be persuasive.

However, the claims require the distal portion of the inner member to remain distal of the distal end of the recovery sheath when the two catheters are advanced along the guide wire. The only portion of the inner catheter of the Daniel device which arguably meets this requirement is the short tapered tip portion 180.

The error in the Examiner's position is further exemplified in statements made in the Advisory Action dated April 22, 2006 (Exhibit 14). In that Advisory Action, the Examiner states as follows:

> Clearly a length of this tube (172) extends distally beyond the sheath (150). The figures show only one of the many possible relevant positions between the components, so the inner tube could be moved to extend farther beyond the sheath.

However, the Examiner is entirely wrong in making these statements. The inner catheter 172 cannot possibly be moved to extend any further beyond the sheath than is shown in figures 20 or 23. This is due to the fact that the control handles strictly limits the relative movement between the inner catheter 172 and outer retrieval catheter 150 in the Daniel device. In this fashion, the control handles depicted in figures 24-26 actually prevent the inner catheter 172 from extending any further past the distal end of the retrieval catheter as is shown in either figure 20 or 23. (See figures 24-26 and Col. 9, l. 51-Col. 11, l. 2 of Daniel et al.). More specifically, figure 24 shows the position of the control handles when the inner catheter is extended at its most distal with respect to the outer retrieval catheter. Again, the positioning of the inner catheter 172 relative to outer retrieval catheter 150 is depicted in figures 20 and 23 of Daniel et al. The construction of the control handles prevent the tapered tip portion 180 from extending any further than is depicted in figures 20 and 23. Figure 25 shows the control handles when the outer retrieval catheter 150 is moved distally to extend over the filter 21. In this position, the entire distal end

of the inner catheter would be covered, not uncovered, by the retrieval catheter 150. Therefore, the distal end of the inner catheter cannot possibly be moved to extend further beyond the retrieval sheath as stated by the Examiner. Therefore, the Examiner's position is incorrect.

Appellants further submit that the recovery system of Daniel et al. actually teaches away from the use of a length of tubing which extend beyond the distal end of the recovery catheter. In the Daniel recovery system, the transversely enlarged insert 176 must fill the inside diameter of the housing 152 in order to prevent the distal end 157 of the recovery catheter from "snowplowing" into the wall of the body vessel as the catheter is advanced over the guide wire. If the distal end of the inner catheter 172 of the Daniel device was extended further out of the housing 152 of the retrieval catheter 150, then the insert 176 would be pushed out of the housing 152. Such position of the inner and outer catheters would simply eliminate the function of the insert 176.

Accordingly, it is urged that independent claims 35, 45 and 54 and therefore all claims depending therefrom avoid anticipation and that the rejection of claims 35-40, 42-50 and 52-67 and 70-74 under 35 U.S.C. § 102(e) should be reversed.

**ISSUE 2**

In the final Office action dated December 22, 2005, the Examiner rejected claims 68 and 69 under 35 U.S.C. § 102(e) as being anticipated by Daniel et al. (U.S. Patent No. 6,171,327). Claims 68 and 69 are apparatus claims directed to a system for recovering an embolic protection device. Independent claim 68 is similar to claim 45 and includes the recitation of an inner catheter having a distal portion including a flexible tubing of sufficient length which allows the distal end of the recovery catheter to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel. However, claim 68 further recites that the length of flexible tubing is at least as long as the longitudinal length of the expandable filter.

As addressed above, Daniel et al. fails to disclose the basic structure which requires the inner catheter to have a distal portion including a length of flexible tubing having sufficient length to reduce the possibility that the recovery sheath will straighten the body vessel once advanced over the length of tubing. Claim 68 also requires the length of flexible tubing to be at

least as long as the longitudinal length of the expandable filter. As addressed above, the only portion of the inner catheter of the Daniel device which extends beyond the distal end of the outer catheter is the small tapered tip 180 of the insert 176. Even assuming arguendo that this tapered tip 180 constitutes a length of tubing, it certainly does not have a length at least as long as the longitudinal length of the filter device depicted in figures 20-23 of Daniel et al.

Accordingly, it is urged that independent claim 68 and its dependent claim 69 avoid anticipation and that the rejection of claims 68 and 69 under 35 U.S.C. § 102(e) should be reversed.

**ISSUE 3**

In the final Office Action dated December 22, 2005, claims 41 and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Daniel et al. in view of Heyn et al. Claims 41 and 51 require the control handle of the inner catheter to be coaxially disposed within a lumen of the control handle of the outer sheath. The Examiner asserts that Daniel et al. discloses the invention substantially as claimed while relying on Heyn et al. for the limitation of using a control handle for an inner catheter that can be disposed within the control handle of the outer sheath. Appellants maintain that neither Daniel et al. nor the secondary reference suggest a recovery system having an inner catheter with a distal portion including a flexible tubing of sufficient length which allows the distal end of the recovery catheter to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel. Since the Daniel patent lacks the basic components recited in the claims, as addressed above, its combination with Heyn fails to achieve the structure recited in these claims. The teachings of Heyn et al. fail to supply the missing structure from Daniel and thus, Heyn et al. fails to fulfill the shortcomings of Daniel et al.

Accordingly, it is urged that dependent claims 41 and 51 avoid obviousness and that the rejection of these claims under 35 U.S.C. § 103(a) should be reversed.

## ISSUE 4

In the final Office Action dated December 22, 2005, claim 38 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Daniel et al. Claim 38 requires the inner catheter to have greater column strength than the recovery sheath. The Examiner acknowledges that Daniel et al. fails to state that the inner catheter has greater column strength than the recovery sheath. However, the Examiner takes the position that at the time the invention was made, it would have been an obvious matter of design choice to form the inner catheter with greater column strength. However, there appears to be no motivation for such a design choice. "Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of the reference." In re Kotzab, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000). No suggestion or modification of the materials making up the inner catheter and outer recovery sheath is discernible in Daniel et al. In fact, quite the opposite is true as evidenced by the Examiner's statement in paragraph 2 of the final Office Action dated December 22, 2005, which reads as follows:

> "As evidenced by the fact that the recovery sheath (151) is capable of deforming the distal end (180, 280) of the inner catheter when pushed distal to retrieve the filter, the distal portion of the inner catheter is more flexible than the recovery sheath (151)"

One skilled in the art would thus manufacture the inner catheter to have less column strength than the outer recovery sheath in order to achieve this deformation function.

Accordingly, it is urged that claim 38 avoids obviousness and that the rejection of this claim under 35 U.S.C. § 103(a) should be reversed.

## CONCLUSION

For the foregoing reasons, it is submitted that the present invention as claimed is not anticipated by Daniel et al. and that the Examiner's rejections of claims 35-37, 39-40, 42-50 and 51-74 were erroneous. Further, it is submitted that the present invention as claimed is not obvious and that the Examiner's rejections of claims 38, 41 and 51 were erroneous. Appellants respectfully request reversal of the rejection of claims 35-74.

## VIII. CLAIMS APPENDIX

PLEASE SEE EXHIBIT 1.

## IX. EVIDENCE EXHIBIT

| EXHIBIT | DESCRIPTION |
|---|---|
| 1. | Appealed Claims |
| 2. | U.S. Patent Nos. 6,171,327; and 5,201,757 |
| 3. | Preliminary Amendment dated September 15, 2003 |
| 4. | First Office Action dated September 24, 2004 |
| 5. | Amendment Dated December 20, 2004 |
| 6. | Final Office Action Dated March 14, 2005 |
| 7. | Amendment Dated May 12, 2005 |
| 8. | Advisory Action dated June 10, 2005 |
| 9. | RCE dated June 14, 2005 |
| 10. | Third Office Action dated July 7, 2005 |
| 11. | Amendment Dated October 7, 2005 |
| 12. | Final Office Action dated December 22, 2005 |
| 13. | Response dated February 21, 2006 |
| 14. | Advisory Action Dated March 29, 2005 |
| 15. | Pre-Appeal Brief Request for Review dated May 1, 2006 |
| 16. | Notice of Appeal Dated May 1, 2006 |

## X. RELATED PROCEEDINGS EXHIBIT

NONE

In the event there are any further charges associated with the filing of the subject Appeal Brief, the Director of Patents and Trademarks is hereby authorized to charge our Deposit Account No. 06-2425.

Respectfully submitted,

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**CLAIMS ON APPEAL:**

1 – 34 (Canceled).

35. (Previously presented) A system for recovering an embolic protection device which includes a guide wire and expandable filter disposed thereon from a body vessel, comprising:

an inner catheter having a distal portion and a proximal end and being moveable along the guide wire, the distal portion including a length of flexible tubing;

a control handle attached to the proximal end of the inner catheter;

a recovery sheath having a distal end and a proximal end; and

a control handle attached to the proximal end of the recovery sheath, wherein the inner catheter is capable of being loaded inside the recovery sheath with the distal portion of the inner catheter extending distally beyond the distal end of the recovery sheath when the inner catheter and recovery sheath are being advanced along the guide wire for placement in proximity to the expandable filter of the embolic protection device, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel.

36. (Original) The system of claim 35, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

37. (Original) The system of claim 35, wherein:

the recovery sheath has greater column strength than the inner catheter.

38. (Original) The system of claim 35, wherein:

the inner catheter has greater column strength than the recovery sheath.

39. (Original) The system of claim 35, further including:

a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

40. (Original) The system of claim 35, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

41. (Original) The system of claim 35, wherein:

the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

42. (Original) The system of claim 41, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

43. (Original) The system of claim 42, wherein:

the control handle of the inner catheter is movable relative to the control handle of the recovery sheath.

44. (Original) The system of claim 35, further including:

means for locking the inner catheter onto the guide wire.

45. (Previously Presented) An embolic protection system for deployment in a body vessel, comprising:

a guide wire having a distal end;

an expandable filter located near the distal end of the guide wire;

an inner catheter having a distal portion and a control handle located at a proximal end, wherein the inner catheter is capable of being introduced over the guide wire and the distal portion includes length of flexible tubing; and

a recovery sheath having a distal end and a control handle located at a proximal end, wherein the inner catheter is capable of being loaded inside of a lumen of the recovery sheath, wherein the distal portion of the inner catheter extends distally beyond the distal end of recovery sheath when being advanced along the guide wire to retrieve the expandable filter, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility

that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel.

46. (Original) The system of claim 45, wherein:
the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

47. (Original) The system of claim 45, wherein:
the recovery sheath has greater column strength than the inner catheter.

48. (Original) The system of claim 45, wherein:
the inner catheter has greater column strength than the recovery sheath.

49. (Original) The system of claim 45, further including:
a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

50. (Original) The system of claim 45, wherein:
the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

51. (Original) The system of claim 45, wherein:
the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

52. (Original) The system of claim 51, wherein:
the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

53. (Original) The system of claim 52, wherein:
the control handle of the inner catheter is movable relative to the control handle of the recovery sheath and further including means for locking the control handles together.

54. (Previously Presented) A method of re covering an embolic protection device which includes a guide wire and an expandable filter from a body vessel, comprising:

loading an inner catheter inside a recovery sheath, wherein the inner catheter has a distal portion which extends beyond the distal end of the recovery sheath, the distal portion including a length of flexible tubing having sufficient length to allow the distal end of a recovery sheath to pass thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel;

introducing the inner catheter and recovery sheath over the guide wire;

advancing the distal end of the inner catheter to a position adjacent to the expanded filter;

locking the inner catheter onto the guide wire;

tracking the recovery sheath over the distal portion of the inner catheter and the expanded filter to collapse the expanded filter.

55. (Original) The method of claim 54, further comprising:

removing the recovery sheath, inner catheter, and embolic protection device from the body vessel.

56. (Original) The method of claim 54, wherein:

the recovery sheath may be up to approximately 15 centimeters shorter than the inner catheter.

57. (Original) The method of claim 54, wherein:

the distal portion of the inner catheter may extend up to 10 centimeters beyond the distal end of the recovery sheath when being advanced over the guide wire.

58. (Original) The method of claim 54, wherein:

a control handle is located at the proximal end of the inner catheter and a control handle located at the proximal end of the recovery sheath.

59. (Original) The method of claim 58, wherein:

the control handle of the inner catheter can be locked to the control handle of the recovery sheath.

60. (Original) The method of claim 54, wherein:

after the distal end of the inner catheter is advanced to a position adjacent to the expanded filter, a torque control device is attached to the guide wire and placed in an abutting relationship with the proximal end of the inner catheter to lock the inner catheter onto the guide wire.

61. (Original) The method of claim 58, wherein:

after the distal end of the inner catheter is advanced to a position adjacent to the expanded filter, a torque control device is attached to the guide wire and placed in an abutting relationship with the control handle of the inner catheter to lock the inner catheter onto the guide wire.

62. (Original) The method of claim 58, wherein:

control handle of the recovery sheath is advanced distally to position the recovery sheath over the distal portion of the inner catheter and the expanded filter to collapse the expanded filter.

63. (Previously Presented) The system of claim 35, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

64. (Previously Presented) The system of claim 35, wherein:

the flexible tubing of the distal portion of the inner catheter is more flexible than the recovery sheath.

65. (Previously Presented) The system of claim 45, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

66. (Previously Presented) The system of claim 35, wherein:

the flexible tubing of the distal portion of the inner catheter is more flexible than the recovery sheath.

67. (Previously Presented) The method of claim 54, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

68. (Previously Presented) An embolic protection system for deployment in a body vessel, comprising:

a guide wire having a distal end;

an expandable filter having a particular longitudinal length located near the distal end of the guide wire;

an inner catheter having a distal portion and a control handle located at a proximal end, wherein the inner catheter is capable of being introduced over the guide wire and the distal portion includes a length of flexible tubing at least as long as the longitudinal length of the expandable filter; and

a recovery sheath having a distal end and a control handle located at a proximal end, wherein the inner catheter is capable of being loaded inside of a lumen of the recovery sheath, wherein the distal portion of the inner catheter extends distally beyond the distal end of recovery sheath when being advanced along the guide wire to retrieve the expandable filter, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel.

69. (Previously Presented) The system of claim 68, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

70. (Previously Presented) The system of claim 45, further including:

a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

71. (Previously Presented) The system of claim 45, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

72. (Previously Presented) The system of claim 45, wherein:

the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

73. (Previously Presented) The system of claim 51, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

74. (Previously Presented) The system of claim 52, wherein:

the control handle of the inner catheter is movable relative to the control handle of the recovery sheath and further including means for locking the control handles together.

Claims as of Final Office Action

1 – 34 (Canceled).

35. (Previously presented) A system for recovering an embolic protection device which includes a guide wire and expandable filter disposed thereon from a body vessel, comprising:

an inner catheter having a distal portion and a proximal end and being moveable along the guide wire, the distal portion including a length of flexible tubing;

a control handle attached to the proximal end of the inner catheter;

a recovery sheath having a distal end and a proximal end; and

a control handle attached to the proximal end of the recovery sheath, wherein the inner catheter is capable of being loaded inside the recovery sheath with the distal portion of the inner catheter extending distally beyond the distal end of the recovery sheath when the inner catheter and recovery sheath are being advanced along the guide wire for placement in proximity to the expandable filter of the embolic protection device, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel.

36. (Original) The system of claim 35, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

37. (Original) The system of claim 35, wherein:

the recovery sheath has greater column strength than the inner catheter.

38. (Original) The system of claim 35, wherein:

the inner catheter has greater column strength than the recovery sheath.

39. (Original) The system of claim 35, further including:

a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

40. (Original) The system of claim 35, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

41. (Original) The system of claim 35, wherein:

the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

42. (Original) The system of claim 41, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

43. (Original) The system of claim 42, wherein:

the control handle of the inner catheter is movable relative to the control handle of the recovery sheath.

44. (Original) The system of claim 35, further including:

means for locking the inner catheter onto the guide wire.

45. (Previously presented) An embolic protection system for deployment in a body vessel, comprising:

a guide wire having a distal end;

an expandable filter located near the distal end of the guide wire;

an inner catheter having a distal portion and a control handle located at a proximal end, wherein the inner catheter is capable of being introduced over the guide wire and the distal portion includes length of flexible tubing; and

a recovery sheath having a distal end and a control handle located at a proximal end, wherein the inner catheter is capable of being loaded inside of a lumen of the recovery sheath, wherein the distal portion of the inner catheter extends distally beyond the distal end of recovery sheath when being advanced along the guide wire to retrieve the expandable filter, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel.

46. (Original) The system of claim 45, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

47. (Original) The system of claim 45, wherein:

the recovery sheath has greater column strength than the inner catheter.

48. (Original) The system of claim 45, wherein:

the inner catheter has greater column strength than the recovery sheath.

49. (Original) The system of claim 45, further including:

a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

50. (Original) The system of claim 45, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

51. (Original) The system of claim 45, wherein:

the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

52. (Original) The system of claim 51, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

53. (Original) The system of claim 52, wherein:

the control handle of the inner catheter is movable relative to the control handle of the recovery sheath and further including means for locking the control handles together.

54. (Previously presented) A method of re covering an embolic protection device which includes a guide wire and an expandable filter from a body vessel, comprising:

loading an inner catheter inside a recovery sheath, wherein the inner catheter has a distal portion which extends beyond the distal end of the recovery lumen, the distal portion including a length of flexible tubing having sufficient length to allow the distal end of a recovery sheath to pass thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel;

introducing the inner catheter and recovery sheath over the guide wire;

advancing the distal end of the inner catheter to a position adjacent to the expanded filter;

locking the inner catheter onto the guide wire;

tracking the recovery sheath over the distal portion of the inner catheter and the expanded filter to collapse the expanded filter.

55. (Original) The method of claim 54, further comprising:

removing the recovery sheath, inner catheter, and embolic protection device from the body vessel.

56. (Original) The method of claim 54, wherein:

the recovery sheath may be up to approximately 15 centimeters shorter than the inner catheter.

57. (Original) The method of claim 54, wherein:

the distal portion of the inner catheter may extend up to 10 centimeters beyond the distal end of the recovery sheath when being advanced over the guide wire.

58. (Original) The method of claim 54, wherein:

a control handle is located at the proximal end of the inner catheter and a control handle located at the proximal end of the recovery sheath.

59. (Original) The method of claim 58, wherein:

the control handle of the inner catheter can be locked to the control handle of the recovery sheath.

60. (Original) The method of claim 54, wherein:

after the distal end of the inner catheter is advanced to a position adjacent to the expanded filter, a torque control device is attached to the guide wire and placed in an abutting relationship with the proximal end of the inner catheter to lock the inner catheter onto the guide wire.

61. (Original) The method of claim 58, wherein:

after the distal end of the inner catheter is advanced to a position adjacent to the expanded filter, a torque control device is attached to the guide wire and placed in an abutting relationship with the control handle of the inner catheter to lock the inner catheter onto the guide wire.

62. (Original) The method of claim 58, wherein:

control handle of the recovery sheath is advanced distally to position the recovery sheath over the distal portion of the inner catheter and the expanded filter to collapse the expanded filter.

63. (Previously Presented) The system of claim 35, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

64. (Previously Presented) The system of claim 35, wherein:

the flexible tubing of the distal portion of the inner catheter is more flexible than the recovery sheath.

65. (Previously Presented) The system of claim 45, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

66. (Previously Presented) The system of claim 35, wherein:

the flexible tubing of the distal portion of the inner catheter is more flexible than the recovery sheath.

67. (Previously Presented) The method of claim 54, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

68. (Previously Presented) An embolic protection system for deployment in a body vessel, comprising:

a guide wire having a distal end;

an expandable filter having a particular longitudinal length located near the distal end of the guide wire;

an inner catheter having a distal portion and a control handle located at a proximal end, wherein the inner catheter is capable of being introduced over the guide wire and the distal portion includes a length of flexible tubing at least al long as the longitudinal length of the expandable filter; and

a recovery sheath having a distal end and a control handle located at a proximal end, wherein the inner catheter is capable of being loaded inside of a lumen of the recovery sheath, wherein the distal portion of the inner catheter extends distally beyond the distal end of recovery sheath when being advanced along the guide wire to retrieve the expandable filter, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel.

69. (Previously Presented) The system of claim 68, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

70. (Previously Presented) The system of claim 45, further including:

a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

71. (Previously Presented) The system of claim 45, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

72. (Previously Presented) The system of claim 45, wherein:

the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

73. (Previously Presented) The system of claim 51, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

74. (Previously Presented) The system of claim 52, wherein:

the control handle of the inner catheter is movable relative to the control handle of the recovery sheath and further including means for locking the control handles together.



84292.1

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on September 15, 2003.

Thomas H. Majcher, Reg. No. 31,119



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|---|---|---|
| Appl. No. | : | NEW DIVISIONAL APPLICATION |
| Div of Serial No. | : | 09/845,758, Filed: April 30, 2001 |
| Applicant | : | Boyle et al. |
| Filed | : | Herewith |
| Prior Art Unit | : | Unassigned |
| Prior Examiner | : | Unassigned |
| Title | : | Deployment and Recovery Control Systems for Embolic Protection Devices |
| Docket No.: | : | ACS 65470 (2309D) |
| Customer No. | | 24201 |
| Express Mail No. | : | **EV 327060964 US** |

September 15, 2003
Los Angeles, California

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Dear Sir:

Please enter the following preliminary amendment for the above identified divisional application under 37 C.F.R. § 1.53(b), filed simultaneously herewith. Entry of the following amendment prior to examination of the application is respectfully requested.

IN THE SPECIFICATION

Please amend the specification as follows. On page 1, immediately after the title of the invention and before paragraph [001], please insert the following new paragraph:

CROSS-REFERENCE TO RELATED APPLICATIONS

This is a divisional application of co-pending parent application having U.S. Serial No. 09/845,758, filed April 30, 2001, the contents of which are hereby incorporated by reference.

IN THE CLAIMS

Claims 1 – 34 (Canceled).

35. (Original) A system for recovering an embolic protection device which includes a guide wire and expandable filter disposed thereon, comprising:

an inner catheter having a distal portion and a proximal end and being moveable along the guide wire;

a control handle attached to the proximal end of the inner catheter;

a recovery sheath having a distal end and a proximal end; and

a control handle attached to the proximal end of the recovery sheath, wherein the inner catheter is capable of being loaded inside the recovery sheath with the distal portion of the inner catheter extending distally beyond the distal end of the recovery sheath when the inner catheter and recovery sheath are being advanced along the guide wire for placement in proximity to the expandable filter of the embolic protection device, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter.

36. (Original) The system of claim 35, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

37. (Original) The system of claim 35, wherein:

the recovery sheath has greater column strength than the inner catheter.

38. (Original) The system of claim 35, wherein:

the inner catheter has greater column strength than the recovery sheath.

39. (Original) The system of claim 35, further including:

a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

40. (Original) The system of claim 35, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

41. (Original) The system of claim 35, wherein:

the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

42. (Original) The system of claim 41, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

43. (Original) The system of claim 42, wherein:

the control handle of the inner catheter is movable relative to the control handle of the recovery sheath.

44. (Original) The system of claim 35, further including:

means for locking the inner catheter onto the guide wire.

45. (Original) An embolic protection system, comprising:

a guide wire having a distal end;

an expandable filter located near the distal end of the guide wire;

an inner catheter having a distal portion and a control handle located at a proximal end, wherein the inner catheter is capable of being introduced over the guide wire; and

a recovery sheath having a distal end and a control handle located at a proximal end, wherein the inner catheter is capable of being loaded inside of a lumen of the recovery sheath, wherein the distal portion of the inner catheter extends distally beyond the distal end of recovery sheath when being advanced along the guide wire to retrieve the expandable filter, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter.

46. (Original) The system of claim 45, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

47. (Original) The system of claim 45, wherein:

the recovery sheath has greater column strength than the inner catheter.

48. (Original) The system of claim 45, wherein:

the inner catheter has greater column strength than the recovery sheath.

49. (Original) The system of claim 45, further including:

a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

50. (Original) The system of claim 45, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

51. (Original) The system of claim 45, wherein:

the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

52. (Original) The system of claim 51, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

53. (Original) The system of claim 52, wherein:

the control handle of the inner catheter is movable relative to the control handle of the recovery sheath and further including means for locking the control handles together.

54. (Original) A method of recovering an embolic protection device which includes a guide wire and an expandable filter from a body vessel, comprising:

loading an inner catheter inside a recovery sheath, wherein the inner catheter has a distal portion which extends beyond the distal end of the recovery lumen;

introducing the inner catheter and recovery sheath over the guide wire;

advancing the distal end of the inner catheter to a position adjacent to the expanded filter;

locking the inner catheter onto the guide wire;

advancing the recovery sheath over the distal portion of the inner catheter and the expanded filter to collapse the expanded filter.

55. (Original) The method of claim 54, further comprising:

removing the recovery sheath, inner catheter, and embolic protection device from the body vessel.

56. (Original) The method of claim 54, wherein:

the recovery sheath may be up to approximately 15 centimeters shorter than the inner catheter.

57. (Original) The method of claim 54, wherein:

the distal portion of the inner catheter may extend up to 10 centimeters beyond the distal end of the recovery sheath when being advanced over the guide wire.

58. (Original) The method of claim 54, wherein:

a control handle is located at the proximal end of the inner catheter and a control handle located at the proximal end of the recovery sheath.

59. (Original) The method of claim 58, wherein:

the control handle of the inner catheter can be locked to the control handle of the recovery sheath.

60. (Original) The method of claim 54, wherein:

after the distal end of the inner catheter is advanced to a position adjacent to the expanded filter, a torque control device is attached to the guide wire and placed in an abutting relationship with the proximal end of the inner catheter to lock the inner catheter onto the guide wire.

61. (Original) The method of claim 58, wherein:

after the distal end of the inner catheter is advanced to a position adjacent to the expanded filter, a torque control device is attached to the guide wire and placed in an abutting relationship with the control handle of the inner catheter to lock the inner catheter onto the guide wire.

62. (Original) The method of claim 58, wherein:

control handle of the recovery sheath is advanced distally to position the recovery sheath over the distal portion of the inner catheter and the expanded filter to collapse the expanded filter.

REMARKS

Applicants submit this Preliminary Amendment simultaneously with the enclosed divisional application under Rule § 1.53(b). In this Preliminary Amendment, Applicants have canceled claims 1-34 without prejudice. After entry of this amendment, claims 35-62 are pending in the present divisional application.

The enclosed application papers are copies of the text and documents originally filed in the parent application.

Enclosed is the filing fee of $894.00 due with this filing. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 06-2425 in connection with this paper. A duplicate copy of this paper is enclosed.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By: _____

Thomas H. Majcher
Registration No. 31,119

THM:mjm

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/662,697 | 09/15/2003 | William J. Boyle | ACS 65470 (2309D) | 9777 |

24201 7590 09/24/2004

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| EXAMINER | |
|---|---|
| WEBB, SARAH K | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3731 | |

DATE MAILED: 09/24/2004

Response Due December 24, 2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 10/662,697 | Applicant(s) BOYLE ET AL. | |
|---|---|---|---|
| | Examiner Sarah K Webb | Art Unit 3731 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 35-62 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 35-62 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 35-40,42-50,52-54,58-62 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,171,327 to Daniel et al.

Daniels illustrates a catheter system in Figures 20-23 that is designed for recovery of an embolic filter (21) that is disposed on a guide wire (26). The retrieval device includes an inner catheter (172 in Figure 20 or 372 in Figure 23) that extends distally beyond a recovery sheath (151). The inner catheter can be constructed to have either greater or less column strength than the recovery sheath, as evidenced by the various configurations of Figures 20 and 23. Each catheter has a control handle attached to its proximal end, and the handles are illustrated in Figures 24-26. Control handle 702 is connected to the proximal end of the recovery sheath (151) and control handle 710 is connected to the proximal end of the inner catheter (372).

Inner catheter (372) can be locked onto the guide wire (26) by way of a threaded connection between the handle (710) and a locking mechanism that includes a guide wire clamp (720) and a collet (718). The recovery sheath control handle (702) is locked with the inner catheter control handle (710) by a stop (708) that prevents the handles

(702,710) from becoming separated but allows the handles to slide relative to one another.

Regarding claims 36,46,56, and 57, the language "may be up to", "may be up to approximately", and "may extend up to" is significantly broad to include any length less than the stated dimension. Therefore, the Daniel device meets this limitation, since the recovery sheath is clearly shorter than the inner catheter.

Daniel discloses steps of using the device in column 10 that include advancing the inner catheter and recovery sheath over a guide wire, locking the inner catheter to the guide wire, advancing the recovery sheath over the filter to collapse it, and removing the entire system from the patient's body.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 41 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel in view of US Patent No. 5,201,757 to Heyn et al.

Daniel includes all the limitations of claims 41 and 51, except that the position of the handles is switched so that control handle of the recovery sheath is coaxially disposed within the lumen of the control handle of the inner catheter. Heyn discloses a device with control handles for sheaths that move relative to one another. Heyn teaches that the control handle (60) for the inner catheter (44) can be disposed within

the control handle (56) of the outer sheath (20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to simply rearrange the control handles of Daniel so that the control handle of the inner catheter is disposed within the lumen of the recovery sheath handle, as Heyn teaches that this is an alternate way to configure control handles of relatively moving sheaths.

***Conclusion***

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 6,569,184 to Huter is significantly similar to the claimed invention. US Patent 6,371,971 to Tsugita discloses various embodiments of a filter retrieval device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 605-1176. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhthuan T. Nguyen can be reached on (703) 308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
09/21/2004

DAVID O. REIP
PRIMARY EXAMINER

| Notice of References Cited | Application/Control No. 10/662,697 | Applicant(s)/Patent Under Reexamination BOYLE ET AL. | |
|---|---|---|---|
| | Examiner Sarah K Webb | Art Unit 3731 | Page 1 of 1 |

**U.S. PATENT DOCUMENTS**

| * | | Document Number Country Code-Number-Kind Code | Date MM-YYYY | Name | Classification |
|---|---|---|---|---|---|
| | A | US-6,171,327 | 01-2001 | Daniel et al. | 606/200 |
| | B | US-5,201,757 | 04-1993 | Heyn et al. | 606/200 |
| | C | US-6,371,971 | 04-2002 | Tsugita et al. | 606/200 |
| | D | US-6,569,184 | 05-2003 | Huter, Benjamin C. | 606/200 |
| | E | US- | | | |
| | F | US- | | | |
| | G | US- | | | |
| | H | US- | | | |
| | I | US- | | | |
| | J | US- | | | |
| | K | US- | | | |
| | L | US- | | | |
| | M | US- | | | |

**FOREIGN PATENT DOCUMENTS**

| * | | Document Number Country Code-Number-Kind Code | Date MM-YYYY | Country | Name | Classification |
|---|---|---|---|---|---|---|
| | N | | | | | |
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| | Q | | | | | |
| | R | | | | | |
| | S | | | | | |
| | T | | | | | |

**NON-PATENT DOCUMENTS**

| * | | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
|---|---|---|
| | U | |
| | V | |
| | W | |
| | X | |

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on December 20, 2004.

Thomas H. Majcher, Reg. No. 31,119


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|---|---|---|---|
| Appln. No. | : | 10/662,697 | Confirmation No. 9777 |
| Applicant | : | William J. Boyle, et al. | |
| Filed | : | September 15, 2003 | |
| Art Unit | : | 3731 | |
| Examiner | : | Webb, Sarah K. | |
| Title | : | DEPLOYMENT AND RECOVERY CONTROL SYSTEMS FOR EMBOLIC PROTECTION DEVICES | |
| Docket No.: | : | ACS 65470 (2309D) | Los Angeles, California |
| Customer No. | : | 24201 | December 20, 2004 |

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Dear Sir:

This Amendment is responsive to the Office Action of September 24, 2004, the response for which is due December 27, 2004.

Claims start on page 2.

Remarks start on page 8.

AMENDMENTS TO THE CLAIMS:

The listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

Claims 1 – 34 (Canceled).

35. (Currently Amended) A system for recovering an embolic protection device which includes a guide wire and expandable filter disposed thereon, comprising:

an inner catheter having a distal portion and a proximal end and being moveable along the guide wire, the distal portion including a length of flexible tubing;

a control handle attached to the proximal end of the inner catheter;

a recovery sheath having a distal end and a proximal end; and

a control handle attached to the proximal end of the recovery sheath, wherein the inner catheter is capable of being loaded inside the recovery sheath with the distal portion of the inner catheter extending distally beyond the distal end of the recovery sheath when the inner catheter and recovery sheath are being advanced along the guide wire for placement in proximity to the expandable filter of the embolic protection device, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter.

36. (Original) The system of claim 35, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

37. (Original) The system of claim 35, wherein:

the recovery sheath has greater column strength than the inner catheter.

38. (Original) The system of claim 35, wherein:
the inner catheter has greater column strength than the recovery sheath.

39. (Original) The system of claim 35, further including:
a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

40. (Original) The system of claim 35, wherein:
the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

41. (Original) The system of claim 35, wherein:
the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

42. (Original) The system of claim 41, wherein:
the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

43. (Original) The system of claim 42, wherein:
the control handle of the inner catheter is movable relative to the control handle of the recovery sheath.

44. (Original) The system of claim 35, further including:
means for locking the inner catheter onto the guide wire.

45. (Currently Amended) An embolic protection system, comprising:
a guide wire having a distal end;
an expandable filter located near the distal end of the guide wire;

an inner catheter having a distal portion and a control handle located at a proximal end, wherein the inner catheter is capable of being introduced over the guide wire and the distal portion includes length of flexible tubing; and

a recovery sheath having a distal end and a control handle located at a proximal end, wherein the inner catheter is capable of being loaded inside of a lumen of the recovery sheath, wherein the distal portion of the inner catheter extends distally beyond the distal end of recovery sheath when being advanced along the guide wire to retrieve the expandable filter, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter.

46. (Original) The system of claim 45, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

47. (Original) The system of claim 45, wherein:

the recovery sheath has greater column strength than the inner catheter.

48. (Original) The system of claim 45, wherein:

the inner catheter has greater column strength than the recovery sheath.

49. (Original) The system of claim 45, further including:

a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

50. (Original) The system of claim 45, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

51. (Original) The system of claim 45, wherein:

the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

52. (Original) The system of claim 51, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

53. (Original) The system of claim 52, wherein:

the control handle of the inner catheter is movable relative to the control handle of the recovery sheath and further including means for locking the control handles together.

54. (Currently Amended) A method of recovering an embolic protection device which includes a guide wire and an expandable filter from a body vessel, comprising:

loading an inner catheter inside a recovery sheath, wherein the inner catheter has a distal portion which extends beyond the distal end of the recovery lumen, the distal portion including a length of flexible tubing ;

introducing the inner catheter and recovery sheath over the guide wire;

advancing the distal end of the inner catheter to a position adjacent to the expanded filter;

locking the inner catheter onto the guide wire;

advancing the recovery sheath over the distal portion of the inner catheter and the expanded filter to collapse the expanded filter.

55. (Original) The method of claim 54, further comprising:

removing the recovery sheath, inner catheter, and embolic protection device from the body vessel.

56. (Original) The method of claim 54, wherein:

the recovery sheath may be up to approximately 15 centimeters shorter than the inner catheter.

57. (Original) The method of claim 54, wherein:

the distal portion of the inner catheter may extend up to 10 centimeters beyond the distal end of the recovery sheath when being advanced over the guide wire.

58. (Original) The method of claim 54, wherein:

a control handle is located at the proximal end of the inner catheter and a control handle located at the proximal end of the recovery sheath.

59. (Original) The method of claim 58, wherein:

the control handle of the inner catheter can be locked to the control handle of the recovery sheath.

60. (Original) The method of claim 54, wherein:

after the distal end of the inner catheter is advanced to a position adjacent to the expanded filter, a torque control device is attached to the guide wire and placed in an abutting relationship with the proximal end of the inner catheter to lock the inner catheter onto the guide wire.

61. (Original) The method of claim 58, wherein:

after the distal end of the inner catheter is advanced to a position adjacent to the expanded filter, a torque control device is attached to the guide wire and placed in an abutting relationship with the control handle of the inner catheter to lock the inner catheter onto the guide wire.

62. (Original) The method of claim 58, wherein:

control handle of the recovery sheath is advanced distally to position the recovery sheath over the distal portion of the inner catheter and the expanded filter to collapse the expanded filter.

63. (New) The system of claim 35, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

64. (New) The system of claim 35, wherein:

the flexible tubing of the distal portion of the inner catheter is more flexible than the recovery sheath.

65. (New) The system of claim 45, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

66. (New) The system of claim 35, wherein:

the flexible tubing of the distal portion of the inner catheter is more flexible than the recovery sheath.

67. (New) The method of claim 54, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

## REMARKS

This Amendment is made in response to the Office Action of September 24, 2004. Claims 35-62 are pending in this application. By this Amendment, Applicants have amended claims 35, 45 and 54 to better define the presently claimed invention. Additionally, new claims 63-67 are being presented. Applicants respectfully reconsideration of all the pending claims in view of the remarks presented below.

Claims 35-40, 42-50, 52-54 and 58-62 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,171,327 to Daniel et al. ("the Daniel patent"). Applicant notes that the pending claimed invention defined in claims 35, 45 and 54 recite an inner catheter having a distal portion that includes a length of flexible tubing. Applicants have carefully reviewed the Daniel patent and note that the inner catheter, which the Examiner has identified as component 172 in FIG. 20 or component 372 in FIG. 23, includes a short distal tapered portion 180 which extends distally beyond the recovery sheath (150). However, this distal tapered portion 180 is simply the end of a large insert 172. This tapered portion 180 extends outside of the recovery housing only a short distance is designed to provide a relatively soft and atraumatic tip. However, the portion of the inner catheter, or insert catheter 172 as it is referred to in the Daniel patent, does not include a distal portion including a length of flexible tubing which extends beyond the distal end of the recovery catheter, as is recited in the pending claims. Applicants' presently claimed invention provides this length of flexible tubing to track over the guidewire and to minimize the possibility of the blood vessel straightening as the larger diameter recovery sheath is advanced over the distal portion of the inner catheter. (see page 17, paragraph 28 of Applicants' specification). This particular structure is simply not shown in the Daniel patent. Quite to the contrary, the tapered portion 180 of the Daniel device is a bulky, short atraumatic tip of large diameter to fill in the space created by the lumen of the housing 152 of the retrieval catheter 150. Accordingly, Applicants believe that the presently claimed invention is neither shown nor suggested in the Daniel patent. Applicants respectfully request the Examiner to withdraw the Daniel patent as an anticipatory reference.

Claims 41 and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Daniel patent in view of U.S. Patent No. 5,201,757 to Heyn et al. ("the Heyn patent"). In view of the remarks addressed above with respect to the presently claimed invention defined by claims 35 and 45, it is believed that the particular combination of the Daniel patent with the Heyn patent fails to achieve the claimed structure. Applicants respectfully request the Examiner to withdraw the obviousness rejections against claims 41 and 51.

Applicants note that claims 55-57 were not rejected by the Examiner. Therefore, it appears that those claims may have been allowable. Regardless, Applicants believe that in view of the remarks above with respect to the remaining pending claims, these claims also would be patentably distinct from the art cited by the Examiner. Allowance of these claims is respectfully requested and Applicants respectfully request that the Examiner indicate whether those claims were allowable as dependent from the originally drafted independent claims or as depending from the currently amended independent claims.

In view of the foregoing, it is respectively urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above amendments and remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By: _____
Thomas H. Majcher
Registration No. 31,119

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UNITED STATES PATENT AND TRADEMARK OFFICE

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/662,697 | 09/15/2003 | William J. Boyle | ACS 65470 (2309D) | 9777 |

24201 7590 03/14/2005

THM

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| EXAMINER | |
|---|---|
| WEBB, SARAH K | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3731 | |

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

FINAL REJECTION

2 - MONTH RESPONSE DUE: May 14, 2005
3 - MONTH RESPONSE DUE: June 14, 2005
NOTICE OF APPEAL DUE:
(6-MONTH PERIOD ENDS) September 14, 2005

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/662,697 | BOYLE ET AL. | |
| | Examiner | Art Unit | |
| | Sarah K Webb | 3731 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *35-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 35-40,42-50, and 52-67 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,171,327 to Daniel et al.

Daniels illustrates a catheter system in Figures 20-23 that is designed for recovery of an embolic filter (21) that is disposed on a guide wire (26). The retrieval device includes an inner catheter (172 in Figure 20 or 372 in Figure 23) that extends distally beyond a recovery sheath (151). The recovery sheath (151) tracks over the distal portion of the inner catheter to retrieve the filter, as shown in Figure 19. The inner catheter can be constructed to have either greater or less column strength than the recovery sheath, as evidenced by the various configurations of Figures 20 and 23. As evidenced by the fact that the recovery sheath (151) is capable of deforming the distal end (180,280) of the inner catheter when pushed distally to retrieve the filter, the distal portion of the inner catheter is more flexible than the recovery sheath (151). Daniels also explains that the distal portion of the inner catheter is made of flexible material (column 8, lines 61-67). Each catheter has a control handle attached to its proximal end, and the handles are illustrated in Figures 24-26. Control handle 702 is connected to the proximal end of the recovery sheath (151) and control handle 710 is connected to the proximal end of the inner catheter (372).

Inner catheter (372) can be locked onto the guide wire (26) by way of a threaded connection between the handle (710) and a locking mechanism that includes a guide wire clamp (720) and a collet (718). The recovery sheath control handle (702) is locked

with the inner catheter control handle (710) by a stop (708) that prevents the handles (702,710) from becoming separated but allows the handles to slide relative to one another.

Regarding claims 36,46,56, and 57, the language "may be up to", "may be up to approximately", and "may extend up to" is significantly broad to include any length less than the stated dimension. Therefore, the Daniel device meets this limitation, since the recovery sheath is clearly shorter than the inner catheter.

Daniel discloses steps of using the device in column 10 that include advancing the inner catheter and recovery sheath over a guide wire, locking the inner catheter to the guide wire, advancing the recovery sheath over the filter to collapse it, and removing the entire system from the patient's body.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 41 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel in view of US Patent No. 5,201,757 to Heyn et al.

Daniel includes all the limitations of claims 41 and 51, except that the position of the handles is switched so that control handle of the recovery sheath is coaxially disposed within the lumen of the control handle of the inner catheter. Heyn discloses a device with control handles for sheaths that move relative to one another. Heyn teaches that the control handle (60) for the inner catheter (44) can be disposed within the control handle (56) of the outer sheath (20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to simply rearrange the control handles of Daniel so that the control handle of the inner catheter is disposed

within the lumen of the recovery sheath handle, as Heyn teaches that this is an alternate way to configure control handles of relatively moving sheaths.

***Response to Arguments***

3. Applicant's arguments filed 12/2/704 have been fully considered but they are not persuasive. Applicant argues that the distal portion of the inner catheter in Figures 20-23 of the Daniels patent does not meet the limitation *"length of flexible tubing"* because it is bulky, short, and tapered. The distal portion (172,180) is part of the inner catheter, which is a flexible tube. Daniels explains that the entire inner catheter, including the distal tapered portion (180), is formed of flexible materials (column 8, lines 61-67). The distal portion has a length. Therefore, the distal portion, regardless of its tapered structure, meets the broad limitation *"length of flexible tubing."*

For clarification, claims 55-57 are rejected by Daniels under 102(e). The exclusion of these claims from the 102 (e) section of the previous office action was a typographical error, but the claims were listed as rejected on the Office Action Summary sheet. For further evidence to this, the examiner had made statements regarding the rejection of claims 55,56, and 57: "Regarding claims 36,46,56, and 57..." and "...removing the entire system from the patient's body."

***Conclusion***

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
3/4/05 SKW

Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on May 12, 2005.

Thomas H. Majcher, Reg. No. 31,119



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|---|---|---|---|
| Appln. No. | : | 10/662,697 | Confirmation No. 9777 |
| Applicant | : | William J. Boyle, et al. | |
| Filed | : | September 15, 2003 | |
| Art Unit | : | 3731 | |
| Examiner | : | Webb, Sarah K. | |
| Title | : | DEPLOYMENT AND RECOVERY CONTROL SYSTEMS FOR EMBOLIC PROTECTION DEVICES | |
| Docket No.: | : | ACSES 65470 (2309D) | Los Angeles, California |
| Customer No. | : | 24201 | May 12, 2005 |

Mail Stop AFTER FINAL
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AFTER FINAL REJECTION

Dear Sir:

This Amendment is responsive to the Final Office Action of March 14, 2005, the response for which is due June 14, 2005.

Claims start on page 2.

Remarks start on page 9.

AMENDMENTS TO THE CLAIMS:

The listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

Claims 1 – 34 (Canceled).

35. (Currently Amended) A system for recovering an embolic protection device which includes a guide wire and expandable filter disposed thereon from a body vessel, comprising:

an inner catheter having a distal portion and a proximal end and being moveable along the guide wire, the distal portion including a length of flexible tubing;

a control handle attached to the proximal end of the inner catheter;

a recovery sheath having a distal end and a proximal end; and

a control handle attached to the proximal end of the recovery sheath, wherein the inner catheter is capable of being loaded inside the recovery sheath with the distal portion of the inner catheter extending distally beyond the distal end of the recovery sheath when the inner catheter and recovery sheath are being advanced along the guide wire for placement in proximity to the expandable filter of the embolic protection device, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to pass thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel.

36. (Original) The system of claim 35, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

37. (Original) The system of claim 35, wherein:
the recovery sheath has greater column strength than the inner catheter.

38. (Original) The system of claim 35, wherein:
the inner catheter has greater column strength than the recovery sheath.

39. (Original) The system of claim 35, further including:
a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

40. (Original) The system of claim 35, wherein:
the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

41. (Original) The system of claim 35, wherein:
the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

42. (Original) The system of claim 41, wherein:
the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

43. (Original) The system of claim 42, wherein:
the control handle of the inner catheter is movable relative to the control handle of the recovery sheath.

44. (Original) The system of claim 35, further including:
means for locking the inner catheter onto the guide wire.

45. (Currently Amended) An embolic protection system for deployment in a body vessel, comprising:

a guide wire having a distal end;

an expandable filter located near the distal end of the guide wire;

an inner catheter having a distal portion and a control handle located at a proximal end, wherein the inner catheter is capable of being introduced over the guide wire and the distal portion includes length of flexible tubing; and

a recovery sheath having a distal end and a control handle located at a proximal end, wherein the inner catheter is capable of being loaded inside of a lumen of the recovery sheath, wherein the distal portion of the inner catheter extends distally beyond the distal end of recovery sheath when being advanced along the guide wire to retrieve the expandable filter, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to pass thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel.

46. (Original) The system of claim 45, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

47. (Original) The system of claim 45, wherein:

the recovery sheath has greater column strength than the inner catheter.

48. (Original) The system of claim 45, wherein:

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50. (Original) The system of claim 45, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

51. (Original) The system of claim 45, wherein:

the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

52. (Original) The system of claim 51, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

53. (Original) The system of claim 52, wherein:

the control handle of the inner catheter is movable relative to the control handle of the recovery sheath and further including means for locking the control handles together.

54. (Currently Amended) A method of re covering an embolic protection device which includes a guide wire and an expandable filter from a body vessel, comprising:

loading an inner catheter inside a recovery sheath, wherein the inner catheter has a distal portion which extends beyond the distal end of the recovery lumen, the distal portion including a length of flexible tubing <u>having sufficient length to allow the distal end of a recovery sheath to pass thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel</u>;

introducing the inner catheter and recovery sheath over the guide wire;

advancing the distal end of the inner catheter to a position adjacent to the expanded filter;

locking the inner catheter onto the guide wire;

advancing the recovery sheath over the distal portion of the inner catheter and the expanded filter to collapse the expanded filter.

55. (Original) The method of claim 54, further comprising:

removing the recovery sheath, inner catheter, and embolic protection device from the body vessel.

56. (Original) The method of claim 54, wherein:

the recovery sheath may be up to approximately 15 centimeters shorter than the inner catheter.

57. (Original) The method of claim 54, wherein:

the distal portion of the inner catheter may extend up to 10 centimeters beyond the distal end of the recovery sheath when being advanced over the guide wire.

58. (Original) The method of claim 54, wherein:

a control handle is located at the proximal end of the inner catheter and a control handle located at the proximal end of the recovery sheath.

59. (Original) The method of claim 58, wherein:

the control handle of the inner catheter can be locked to the control handle of the recovery sheath.

60. (Original) The method of claim 54, wherein:

after the distal end of the inner catheter is advanced to a position adjacent to the expanded filter, a torque control device is attached to the guide wire and placed in an abutting relationship with the proximal end of the inner catheter to lock the inner catheter onto the guide wire.

61. (Original) The method of claim 58, wherein:

after the distal end of the inner catheter is advanced to a position adjacent to the expanded filter, a torque control device is attached to the guide wire and placed in an abutting relationship with the control handle of the inner catheter to lock the inner catheter onto the guide wire.

62. (Original) The method of claim 58, wherein:

control handle of the recovery sheath is advanced distally to position the recovery sheath over the distal portion of the inner catheter and the expanded filter to collapse the expanded filter.

63. (Previously Presented) The system of claim 35, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

64. (Previously Presented) The system of claim 35, wherein:

the flexible tubing of the distal portion of the inner catheter is more flexible than the recovery sheath.

65. (Previously Presented) The system of claim 45, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

66. (Previously Presented) The system of claim 35, wherein:

the flexible tubing of the distal portion of the inner catheter is more flexible than the recovery sheath.

67. (Previously Presented) The method of claim 54, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

## REMARKS

This Amendment is made in response to the Final Office Action of March 14, 2005. Claims 35-67 are pending in this application. By this Amendment, Applicants have amended claims 35, 45 and 54 to better define the presently claimed invention. Applicants respectfully request reconsideration of all the pending claims in view of the remarks presented below.

Claims 35-40, 42-50, 52-67 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,171,327 to Daniel et al. ("the Daniel patent"). Applicant notes that the pending claimed invention defined in claims 35, 45 and 54 recite an inner catheter having a distal portion that includes a length of flexible tubing having sufficient length to allow the distal end of the recovery sheath to pass thereover and reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel. Applicants have carefully reviewed the Daniel patent and note that the inner catheter, which the Examiner has identified as component 172 in FIG. 20 or component 372 in FIG. 23, includes a short distal tapered portion 180 which extends distally beyond the recovery sheath (150). Applicants strongly disagree with the Examiner's position that this tapered tip is a length of tubing which extends beyond the recover sheath. Again, it is Applicants' belief that this distal tapered portion 180 is simply the end of a large insert 172. This tapered portion 180 extends outside of the recovery housing only a short distance is designed to provide a relatively soft and atraumatic tip. However, the portion of the inner catheter, or insert catheter 172 as it is referred to in the Daniel patent, does not include a distal portion including a length of flexible tubing

which extends beyond the distal end of the recovery catheter and has sufficient length to allow the distal end of the recovery sheath to pass thereover while reducing the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel, as is recited in the pending claims. Again, Applicants' presently claimed invention provides this length of flexible tubing to track over the guidewire and to minimize the possibility of the blood vessel straightening as the larger diameter recovery sheath is advanced over the distal portion of the inner catheter. (see page 17, paragraph 28 of Applicants' specification). This particular structure is simply not shown in the Daniel patent. Quite to the contrary, the tapered portion 180 of the Daniel device is only a bulky, short atraumatic tip of large diameter to fill in the space created by the lumen of the housing 152 of the retrieval catheter 150. Accordingly, Applicants believe that the presently claimed invention is neither shown nor suggested in the Daniel patent. Applicants respectfully request the Examiner to withdraw the Daniel patent as an anticipatory reference.

Claims 41 and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Daniel patent in view of U.S. Patent No. 5,201,757 to Heyn et al. ("the Heyn patent"). In view of the remarks addressed above with respect to the presently claimed invention defined by claims 35 and 45, it is believed that the particular combination of the Daniel patent with the Heyn patent fails to achieve the claimed structure. Applicants respectfully request the Examiner to withdraw the obviousness rejections against claims 41 and 51.

In view of the foregoing, it is respectively urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above amendments and remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By: _____

Thomas H. Majcher
Registration No. 31,119

THM:kst
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/662,697 | 09/15/2003 | William J. Boyle | ACS 65470 (2309D) | 9777 |

24201 7590 06/10/2005

THM

FULWIDER PATTON LEE & UTECHT, LLP
HOWARD HUGHES CENTER
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TENTH FLOOR
LOS ANGELES, CA 90045

| EXAMINER | |
|---|---|
| WEBB, SARAH K | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3731 | |

DATE MAILED: 06/10/2005

Advisory Action

Please find below and/or attached an Office communication concerning this application or proceeding.

FINAL REJECTION

2 - MONTH RESPONSE DUE:
3 - MONTH RESPONSE DUE: June 14, 2005
NOTICE OF APPEAL DUE:
(6-MONTH PERIOD ENDS) September 14, 2005

| Advisory Action Before the Filing of an Appeal Brief | Application No. 10/662,697 | Applicant(s) BOYLE ET AL. | |
|---|---|---|---|
| | Examiner Sarah K Webb | Art Unit 3731 | |

*--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

THE REPLY FILED 31 May 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: 35-67.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Julian W. Woo

**JULIAN W. WOO**
**PRIMARY EXAMINER**

Continuation of 3. NOTE: the new claim limitation necessitates further consideration of the prior art.

Doc Code:

PTO/SB/30 (09-04)
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# REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL

Address to:
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Alexandria, VA 22313-1450

| | |
|---|---|
| Application Number | 10/662,697 |
| Filing Date | September 15, 2003 |
| First Named Inventor | William J. Boyle et al. |
| Art Unit | 3731 |
| Examiner Name | Sarah K. Webb |
| Attorney Docket Number | ACSES-65470 (2309D) |

**This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.**
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO ) on page 2.

1. Submission required under 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

a. ☒ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.
   i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
   ii. ☐ Other _____

b. ☐ Enclosed
   i. ☐ Amendment/Reply
   ii. ☐ Affidavit(s)/Declaration(s)
   iii. ☐ Information Disclosure Statement (IDS)
   iv. ☐ Other _____

2. Miscellaneous
a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)
b. ☐ Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.
a. ☒ The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No. 06-2425 . I have enclosed a duplicate copy of this sheet.
   i. ☒ RCE fee required under 37 CFR 1.17(e)
   ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)
   iii. ☐ Other _____
b. ☒ Check in the amount of $ 790.00 enclosed
c. ☐ Payment by credit card (Form PTO-2038 enclosed)

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

## *SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED*

| | | | |
|---|---|---|---|
| Signature | | Date | June 14, 2005 |
| Name (Print / Type) | Thomas H. Majcher | Registration No. | 31,009 |

## *CERTIFICATE OF MAILING OR TRANSMISSION*

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent andTrademark Office on the date shown below.

| | | | |
|---|---|---|---|
| Signature | | | |
| Name (Print / Type) | Thomas H. Majcher | Date | June 14, 2005 |

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing the burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

JUL 11 2005

FULWIDER PA...

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/662,697 | 09/15/2003 | William J. Boyle | ACS 65470 (2309D) | 9777 |

24201 7590 07/07/2005

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THM

| EXAMINER | |
|---|---|
| WEBB, SARAH K | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3731 | |

DATE MAILED: 07/07/2005

Response Due October 7, 2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/662,697 | BOYLE ET AL. | |
| | Examiner | Art Unit | |
| | Sarah K. Webb | 3731 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *35-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 35-38,45-48, and 54-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,569,184 to Huter. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application simply includes obvious limitations such as a control handle on the proximal end of the device and the inner catheter is flexible tubing. The patent and application claim the same inventions, including the recovery device, the apparatus including the recovery device and filter, and the method of retrieving the filter using the recovery device.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 38 and 48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the inner catheter being more flexible than the recovery sheath, does not reasonably provide enablement for the inner catheter having greater column strength than the recovery sheath. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 35-40,42-50, and 52-67 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,171,327 to Daniel et al.

Daniels illustrates a catheter system in Figures 20-23 that is designed for recovery of an embolic filter (21) that is disposed on a guide wire (26). The retrieval device includes an inner catheter (172 in Figure 20 or 372 in Figure 23) that extends distally beyond a recovery sheath (151). Claims 36,46,56,57 are significantly broad enough to encompass any length of either catheter. The recovery sheath (151) tracks over the distal portion of the inner catheter to retrieve the filter, as shown in Figure 19. Daniels explains that the distal portion of the inner catheter is made of flexible material (column 8, lines 61-67). As evidenced by the fact that the recovery sheath

(151) is capable of deforming the distal end (180,280) of the inner catheter when pushed distally to retrieve the filter, the distal portion of the inner catheter is more flexible than the recovery sheath (151). Each catheter has a control handle attached to its proximal end, and the handles are illustrated in Figures 24-26. Control handle 702 is connected to the proximal end of the recovery sheath (151) and control handle 710 is connected to the proximal end of the inner catheter (372).

Inner catheter (372) can be locked onto the guide wire (26) by way of a threaded connection between the handle (710) and a locking mechanism that includes a guide wire clamp (720) and a collet (718). The recovery sheath control handle (702) is locked with the inner catheter control handle (710) by a stop (708) that prevents the handles (702,710) from becoming separated but allows the handles to slide relative to one another.

Regarding claims 36,46,56, and 57, the language *"may be up to"*, *"may be up to approximately"*, and *"may extend up to"* is significantly broad to include any length less than the stated dimension. Therefore, the Daniel device meets this limitation, since the recovery sheath is clearly shorter than the inner catheter.

Daniel discloses steps of using the device in column 10 that include advancing the inner catheter and recovery sheath over a guide wire, locking the inner catheter to the guide wire, advancing the recovery sheath over the filter to collapse it, and removing the entire system from the patient's body.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 41 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel in view of US Patent No. 5,201,757 to Heyn et al.

Daniel includes all the limitations of claims 41 and 51, except that the position of the handles is switched so that control handle of the recovery sheath is coaxially disposed within the lumen of the control handle of the inner catheter. Heyn discloses a device with control handles for sheaths that move relative to one another. Heyn teaches that the control handle (60) for the inner catheter (44) can be disposed within the control handle (56) of the outer sheath (20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to simply rearrange the control handles of Daniel so that the control handle of the inner catheter is disposed within the lumen of the recovery sheath handle, as Heyn teaches that this is an alternate way to configure control handles of relatively moving sheaths.

***Response to Arguments***

5. Applicant's arguments filed 6/17/05 have been fully considered but they are not persuasive. Applicant argues that the distal portion of the inner catheter in Figures 20-23 of the Daniels patent does not meet the limitation *"length of flexible tubing"* because it is bulky, short, and tapered. The distal portion (172,180) is part of the inner catheter, which is a flexible tube. Daniels explains that the entire inner catheter, including the distal tapered portion (180), is formed of flexible materials (column 8, lines 61-67). The distal portion has a length. Therefore, the distal portion,

regardless of its enlarged and tapered structure, meets the broad limitation *"length of flexible tubing."* Further, claims 36,46,56, and 57 recite the phrases *"may be up to"*, *"may be up to approximately"*, and *"may extend up to"*, which are significantly broad enough to encompass any relative lengths of the catheter tubes. Therefore, the Daniel device meets this limitation, since the recovery sheath is clearly shorter than the inner catheter.

Though the inner catheter and outer sheath are shown in a particular position in Figures 20-23, the proximal handles allow the tubes to be moved relative to one another. With the sheath retracted, the distal end of inner catheter would extend further past the distal end of the outer sheath.

The new limitation *"and the distal portion...of the body vessel"* does not provide any positive structural limitations that distinguish the prior art from the claimed invention. The new limitation is significantly broad enough to include any relative lengths of tubing.

***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent No. 6,361,546 to Khosravi discloses a retrieval device for a filter (10) that is adapted to be advanced over a guide wire (68) in Figures 2G and 2H. The device (110) includes an inner catheter (114) with a proximal control handle (118) and a recovery sheath with a proximal control handle (128). The inner catheter is a flexible tube (column 6, line 56).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
6/30/05

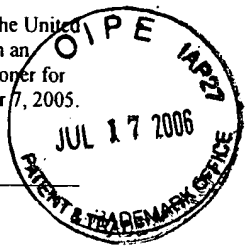
Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on October 7, 2005.

Thomas H. Majcher, Reg. No. 31,119




IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|---|---|---|
| Appl. No. | : | 10/662,697 |
| Applicants | : | William J. Boyle et al. |
| Filed | : | September 15, 2003 |
| Title | : | DEPLOYMENT AND RECOVERY CONTROL SYSTEMS FOR EMBOLIC PROTECTION DEVICES<br>Divisional of U.S. Patent No. 6,645,223 (09/845,758 filed 4/30/01) |
| Art Unit | : | 3731 |
| Examiner | : | Sarah K. Webb |
| Docket No.: | : | ACSES-65470 (2309D) |
| Customer No. | : | 24201 |

Los Angeles, California
October 7, 2005

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Dear Sir:

This Amendment is responsive to the Office action mailed July 7, 2005, a response to which is due October 7, 2005.

Claims start on page 2.

Remarks start on page 11.

IN THE SPECIFICATION:

Please replace paragraph 29 of the specification with the following paragraph:

[29] As shown in FIGS 4 and 5, after the distal end 96 of the inner catheter 72 has reached the proximal fitting 98 which maintains the filter assembly 14 on the guide wire 18, the inner catheter 72 can be then locked into place by the physician. This is accomplished by backloading the torque control device 34 with the wire introducer 42 onto the guide wire 18 and positioning the two components in an abutting relationship with the proximal control handle 82 of the inner catheter 72. Once the torque control device 34 and wire introducer 42 are placed adjacent to the proximal handle 82, the physician can lock the torque control device 34 via the locking mechanism 38 to lock the components onto the wire 18. In this regard, the inner catheter 72 cannot move along the length of the guide wire since the distal end 46 is in an abutting relationship with the proximal fitting 98 and the proximal control handle 82 is in an abutting relationship with the torque control device 34 and wire introducer 32. Once the inner catheter 72 is locked in place, the recovery sheath 76 can now be advanced over the distal portion 78 of the inner catheter 72 and toward the filter assembly 14 in order to collapse and recover the expanded filter assembly 14. The column strength at the distal end 80 of the recovery sheath 76 should be sufficiently strong to ensure that as the struts of the filter assembly 14 are moved back into its collapsed position and that the recovery sheath 76 does not buckle or experience an accordion effect. Alternatively, the column strength of the inner catheter can be greater than the column strength of the recovery sheath.

AMENDMENTS TO THE CLAIMS:

The below listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1 – 34 (Canceled).

35. (Currently Amended) A system for recovering an embolic protection device which includes a guide wire and expandable filter disposed thereon from a body vessel, comprising:

an inner catheter having a distal portion and a proximal end and being moveable along the guide wire, the distal portion including a length of flexible tubing;

a control handle attached to the proximal end of the inner catheter;

a recovery sheath having a distal end and a proximal end; and

a control handle attached to the proximal end of the recovery sheath, wherein the inner catheter is capable of being loaded inside the recovery sheath with the distal portion of the inner catheter extending distally beyond the distal end of the recovery sheath when the inner catheter and recovery sheath are being advanced along the guide wire for placement in proximity to the expandable filter of the embolic protection device, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track ~~pass~~ thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel.

36. (Original) The system of claim 35, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

37. (Original) The system of claim 35, wherein:
the recovery sheath has greater column strength than the inner catheter.

38. (Original) The system of claim 35, wherein:
the inner catheter has greater column strength than the recovery sheath.

39. (Original) The system of claim 35, further including:
a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

40. (Original) The system of claim 35, wherein:
the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

41. (Original) The system of claim 35, wherein:
the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

42. (Original) The system of claim 41, wherein:
the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

43. (Original) The system of claim 42, wherein:
the control handle of the inner catheter is movable relative to the control handle of the recovery sheath.

44. (Original) The system of claim 35, further including:
means for locking the inner catheter onto the guide wire.

45. (Currently Amended) An embolic protection system for deployment in a body vessel, comprising:

a guide wire having a distal end;

an expandable filter located near the distal end of the guide wire;

an inner catheter having a distal portion and a control handle located at a proximal end, wherein the inner catheter is capable of being introduced over the guide wire and the distal portion includes a length of flexible tubing; and

a recovery sheath having a distal end and a control handle located at a proximal end, wherein the inner catheter is capable of being loaded inside of a lumen of the recovery sheath, wherein the distal portion of the inner catheter extends distally beyond the distal end of recovery sheath when being advanced along the guide wire to retrieve the expandable filter, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track ~~pass~~ thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel.

46. (Original) The system of claim 45, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

47. (Original) The system of claim 45, wherein:

the recovery sheath has greater column strength than the inner catheter.

48. (Original) The system of claim 45, wherein:

the inner catheter has greater column strength than the recovery sheath.

49. (Original) The system of claim 45, further including:

a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

50. (Original) The system of claim 45, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

51. (Original) The system of claim 45, wherein:

the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

52. (Original) The system of claim 51, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

53. (Original) The system of claim 52, wherein:

the control handle of the inner catheter is movable relative to the control handle of the recovery sheath and further including means for locking the control handles together.

54. (Currently Amended) A method of re covering an embolic protection device which includes a guide wire and an expandable filter from a body vessel, comprising:

loading an inner catheter inside a recovery sheath, wherein the inner catheter has a distal portion which extends beyond the distal end of the recovery lumen, the distal portion including a length of flexible tubing having sufficient length to allow the distal end of a recovery sheath to pass thereover to reduce the possibility that the

recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel;

introducing the inner catheter and recovery sheath over the guide wire;

advancing the distal end of the inner catheter to a position adjacent to the expanded filter;

locking the inner catheter onto the guide wire;

tracking ~~advancing~~ the recovery sheath over the distal portion of the inner catheter and the expanded filter to collapse the expanded filter.

55. (Original) The method of claim 54, further comprising:

removing the recovery sheath, inner catheter, and embolic protection device from the body vessel.

56. (Original) The method of claim 54, wherein:

the recovery sheath may be up to approximately 15 centimeters shorter than the inner catheter.

57. (Original) The method of claim 54, wherein:

the distal portion of the inner catheter may extend up to 10 centimeters beyond the distal end of the recovery sheath when being advanced over the guide wire.

58. (Original) The method of claim 54, wherein:

a control handle is located at the proximal end of the inner catheter and a control handle located at the proximal end of the recovery sheath.

59. (Original) The method of claim 58, wherein:

the control handle of the inner catheter can be locked to the control handle of the recovery sheath.

60. (Original) The method of claim 54, wherein:

after the distal end of the inner catheter is advanced to a position adjacent to the expanded filter, a torque control device is attached to the guide wire and placed in an abutting relationship with the proximal end of the inner catheter to lock the inner catheter onto the guide wire.

61. (Original) The method of claim 58, wherein:

after the distal end of the inner catheter is advanced to a position adjacent to the expanded filter, a torque control device is attached to the guide wire and placed in an abutting relationship with the control handle of the inner catheter to lock the inner catheter onto the guide wire.

62. (Original) The method of claim 58, wherein:

control handle of the recovery sheath is advanced distally to position the recovery sheath over the distal portion of the inner catheter and the expanded filter to collapse the expanded filter.

63. (Previously Presented) The system of claim 35, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

64. (Previously Presented) The system of claim 35, wherein:

the flexible tubing of the distal portion of the inner catheter is more flexible than the recovery sheath.

65. (Previously Presented) The system of claim 45, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

66. (Previously Presented) The system of claim 35, wherein:

the flexible tubing of the distal portion of the inner catheter is more flexible than the recovery sheath.

67. (Previously Presented) The method of claim 54, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

68. (New) An embolic protection system for deployment in a body vessel, comprising:

a guide wire having a distal end;

an expandable filter having a particular longitudinal length located near the distal end of the guide wire;

an inner catheter having a distal portion and a control handle located at a proximal end, wherein the inner catheter is capable of being introduced over the guide wire and the distal portion includes a length of flexible tubing at least al long as the longitudinal length of the expandable filter; and

a recovery sheath having a distal end and a control handle located at a proximal end, wherein the inner catheter is capable of being loaded inside of a lumen of the recovery sheath, wherein the distal portion of the inner catheter extends distally beyond the distal end of recovery sheath when being advanced along the guide wire to retrieve the expandable filter, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel.

69. (New) The system of claim 68, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

70. (New) The system of claim 45, further including:

a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

71. (New) The system of claim 45, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

72. (New) The system of claim 45, wherein:

the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

73. (New) The system of claim 51, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

74. (New) The system of claim 52, wherein:

the control handle of the inner catheter is movable relative to the control handle of the recovery sheath and further including means for locking the control handles together.

## REMARKS

This Amendment is filed in response to the Office Action of July 7, 2005. Previously, claims 35-67 were pending in this application. By this Amendment, Applicants have amended claims 35, 45 and 54 to better define the presently claimed invention. The amendments to these claims were made for clarification and are not intended to narrow the scope of the claims. New claims 68-74 are now being presented. Applicants respectfully request reconsideration of all the pending claims in view of the remarks presented below.

Initially, the Examiner has rejected claims 38 and 48 under 35 U. S. C. 112, first paragraph. Applicants note that the Specification has now been amended to state that the column strength of the inner catheter could be greater than the recovery sheath. Applicants rely on the disclosure of claims 38 and 48 to support the amendment to the Specification. Therefore, it is believed that no new matter has been introduced into the application. The column strength of the recovery sheath can certainly be less that the inner catheter and will track over the inner catheter while still being sufficiently strong to collapse the expanded filter. Accordingly, Applicants respectfully request the Examiner to withdraw the rejection of claims 38 and 48 under 35 U. S. C. 112, first paragraph.

Claims 35-40, 42-50, 52-67 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,171,327 to Daniel et al. ("the Daniel patent"). Applicants note that the amendment to pending claims 35, 45 and 54 now recite an inner catheter having a distal portion that includes a length of flexible tubing having sufficient length to allow the distal end of the recovery sheath to track thereover and reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a

curved portion of the body vessel. Applicants strongly disagree with the Examiner's position that the catheter shown in the Daniel patent somehow tracks over the component which the Examiner has identified as constituting the flexible length of tubing that forms the distal end of the inner catheter. The Examiner has taken the position that the short tapered portion 180 which extends distally beyond the recovery sheath (150) constitutes the distal end of the inner catheter. However, this tapered portion 180 extends outside of the recovery housing only a short distance and is merely designed to provide a relatively soft and atraumatic tip. However, due to its tapered structure, the outer catheter of the Daniel device does not even contact this tapered tip at all. Therefore, the outer catheter does not track over this distal tip portion in any manner. Moreover, this tip portion 180 certainly does not function in any manner to reduce the possibility that the recovery sheath will straighten the body vessel when advance along the inner catheter when placed in a curved portion of the body vessel.

Applicants' presently claimed invention provides this length of flexible tubing to allow the outer catheter to track thereover to minimize the possibility of the blood vessel straightening as the larger diameter recovery sheath is advanced over the distal portion of the inner catheter. (see page 17, paragraph 28 of Applicants' specification). Such an arrangement of an outer catheter tracking over an inner catheter to reduce straightening of the body vessel is simply not shown in the Daniel patent. Also, in use, the outer catheter of the Daniel device does not even appear to move distally over this tapered tip portion 180 at all. Rather, it appears that the inner catheter actually is retracted proximally to

move the expanded filter back into the retrieval housing 152 of the outer catheter 150. Therefore, the outer catheter of the Daniel patent remains stationary relative to the inner catheter as the two catheters are moved into to body vessel. Once in positioned in the vessel, the outer catheter remains stationary as the inner catheter is retracted proximally to retrieve the expanded filter. This is yet another reason why the outer catheter of the Daniel patent does not, and cannot, track over this tapered tip portion 180. Accordingly, Applicants believe that the presently claimed invention is neither shown nor suggested in the Daniel patent. Applicants respectfully request the Examiner to withdraw the Daniel patent as an anticipatory reference.

Claims 41 and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Daniel patent in view of U.S. Patent No. 5,201,757 to Heyn et al. ("the Heyn patent"). In view of the remarks addressed above with respect to the presently claimed invention defined by claims 35 and 45, it is believed that the particular combination of the Daniel patent with the Heyn patent fails to achieve the claimed structure. Applicants respectfully request the Examiner to withdraw the obviousness rejections against claims 41 and 51.

Finally, newly presented claims 68-74 are believed to be patentable over the Daniel patent for the same reasons that claims 1 and 45 are patentable over that reference.

The Examiner has rejected claims 35-38, 45-48 and 54-57 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1- 17 of U. S. Patent No. 6,569,184. While Applicants believe that the claims at issue

have completely different scope, Applicants submit herewith a Terminal Disclaimer to place this case in a condition for allowance.

In view of the foregoing, it is respectively urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above amendments and remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/662,697 | 09/15/2003 | William J. Boyle | ACS 65470 (2309D) | 9777 |

24201 7590 12/22/2005

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| EXAMINER | |
|---|---|
| WEBB, SARAH K | |
| **ART UNIT** | **PAPER NUMBER** |
| 3731 | |

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

FINAL REJECTION

2 - MONTH RESPONSE DUE: February 22, 2006
3 - MONTH RESPONSE DUE: March 22, 2006
NOTICE OF APPEAL DUE:
(6-MONTH PERIOD ENDS) June 22, 2006

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/662,697 | BOYLE ET AL. | |
| | Examiner | Art Unit | |
| | Sarah K. Webb | 3731 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *35-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Terminal Disclaimer*

1. The terminal disclaimer filed on 10/11/05 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent 6,569,184 to Huter has been reviewed and is accepted. The terminal disclaimer has been recorded.

### *Claim Rejections - 35 USC § 102*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 35-40,42-50, and 52-74 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,171,327 to Daniel et al.

Daniels illustrates a catheter system in Figures 20-23 that is designed for recovery of an embolic filter (21) that is disposed on a guide wire (26). The retrieval device includes an inner catheter (172 in Figure 20 or 372 in Figure 23) that extends distally beyond a recovery sheath (151). Claims 36,46,56,57 are significantly broad enough to encompass any length of either catheter. The recovery sheath (151) tracks over the distal portion of the inner catheter to retrieve the filter, as shown in Figure 19. Daniels explains that the distal portion of the inner catheter is made of flexible material (column 8, lines 61-67). As evidenced by the fact that the recovery sheath (151) is capable of deforming the distal end (180,280) of the inner catheter when pushed distally to retrieve the filter, the distal portion of the inner catheter is more flexible than the recovery sheath (151). Each catheter has a control handle attached to its proximal end, and the handles are illustrated in Figures 24-26. Control handle

702 is connected to the proximal end of the recovery sheath (151) and control handle 710 is connected to the proximal end of the inner catheter (372).

Inner catheter (372) can be locked onto the guide wire (26) by way of a threaded connection between the handle (710) and a locking mechanism that includes a guide wire clamp (720) and a collet (718). The recovery sheath control handle (702) is locked with the inner catheter control handle (710) by a stop (708) that prevents the handles (702,710) from becoming separated but allows the handles to slide relative to one another.

Regarding claims 36,46,56, and 57, the language *"may be up to"*, *"may be up to approximately"*, and *"may extend up to"* is significantly broad to include any length less than the stated dimension. Therefore, the Daniel device meets this limitation, since the recovery sheath is clearly shorter than the inner catheter.

Daniel discloses steps of using the device in column 10 that include advancing the inner catheter and recovery sheath over a guide wire, locking the inner catheter to the guide wire, advancing the recovery sheath over the filter to collapse it, and removing the entire system from the patient's body.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 41 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel in view of US Patent No. 5,201,757 to Heyn et al.

Daniel includes all the limitations of claims 41 and 51, except that the position of the handles is switched so that control handle of the recovery sheath is coaxially

disposed within the lumen of the control handle of the inner catheter. Heyn discloses a device with control handles for sheaths that move relative to one another. Heyn teaches that the control handle (60) for the inner catheter (44) can be disposed within the control handle (56) of the outer sheath (20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to simply rearrange the control handles of Daniel so that the control handle of the inner catheter is disposed within the lumen of the recovery sheath handle, as Heyn teaches that this is an alternate way to configure control handles of relatively moving sheaths.

4. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. Daniels fails to state that the inner catheter has greater column strength than the recovery sheath. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to form the inner catheter to have greater column strength than the recovery sheath, because applicant has not disclosed that the combination of these material properties provide an advantage or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the combination of material properties disclosed by Daniels, because the Daniels device achieves the same objective of tracking a recovery sheath over an inner catheter to retrieve a filter.

***Response to Arguments***

5. Applicant's arguments filed 10/11/05 have been fully considered but they are not persuasive. Applicant argues that the recovery sheath does not "track" over the distal portion of the inner catheter (172) because the distal tip of the catheter is

tapered. The distal portion (172,180) is part of the inner catheter, which is a flexible tube. Examiner does not consider only the tip of the inner catheter to be the distal portion of the inner catheter. The "distal portion" can be any length of the inner catheter distal to the most proximal point. Therefore, the Daniels device includes a length of the inner catheter that is at least as long as the filter. The recovery sheath does "move over" the entire inner catheter, so this argument is not found to be persuasive.

6. Applicant argues that the distal portion of the inner catheter of the Daniels device does not *"reduce the possibility that the recovery sheath will straighten the body vessel..."* Daniels is not required to explicitly state this characteristic of the device. Daniels is only required to meet the structural requirements of the claims. Claim 35 recites *"inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility..."* The claims nor the specification set forth any further characteristics that a device must have in order to be capable of this function. Since Daniels includes all of the structural requirements of the claims, Daniels is considered to meet the claim limitations.

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
12/19/05

JULIAN W. WOO
PRIMARY EXAMINER